C

DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO

6320/H2-134
MED-361/2U234548.A
3 Mar 94

From: Chief, Bureau of Medicine and Surgery

Subj: ASSESSMENT OF RISKS PRESENTED BY FAILURE OF FACILITY SYSTEM SUPPORT

Ref: (a) Accreditation Manual for Hospitals, Joint Commission on the Accreditation of Healthcare Organizations, 1994

1. A recent investigation highlighted the importance of anticipating and planning for facility system failures. I ask your attention to this issue to ensure risk of failures of utility systems which support the patient care environment are adequately assessed.

2. The investigation chronicled the medical care and circumstances surrounding the death of a patient at a Navy hospital. The patient, being maintained on ventilator support, died following two periods of "brown outs". During the two periods of reduced power, the first in excess of 1 hour duration and the second of approximately 4 hours duration, the patient's ventilator system failed to function at full power. It was subsequently discovered that the emergency back-up system would have been activated only with the external power completely shut off as opposed to reduced power or "brown outs". While not triggering the activation of the emergency back-up system the reduced power did, however, by reduced voltage compromise the optimal delivery of the positive end expiratory pressure (PEEP).

3. Reference (a) requires each facility to have ". . . a utilities management program designed to assure the operational reliability, assess the special risks, and respond to failures of utility systems that support the patient care environment." Unfortunately, the risk of reduced power and the potential impact of reduced power had not been identified prior to this occurrence.

D. F. HAGEN

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PUBLICATIONS OF THE COMPRESSED GAS ASSOCIATION

Pamphlet Number	Title
AV-1	Safe Handling & Storage of Compressed Gases
AV-3	Filling of Industrial & Medical Nonflammable Compressed Gas Cylinders
AV-4	Charac. & Safe Handling of Medical Gases
AV-5	Safe Handling of Liquefied Nitrogen & Argon
AV-6	Highway Transport. of Gases
AV-7	Charac. & Safe Handling of Carbon Dioxide
AV-8	Charac. & Safe Handling of Cryogenic Liquid & Gaseous Oxygen
AV-9	Handling Acetylene Cylinders in Fire Situations
AV-10	Safe Handling & Use of Medical Gases & Equipment in a
C-1	Methods for Hydrostatic Testing of Compressed Gas Cylinders
C-3	Standards for Welding on Thin Walled Steel Cylinders
C-4	ANSI Method of Marking Portable Compressed Gas Containers to Identify the Material Contained
C-5	Cylinder Service Life-Seamless Steel High Pressure Cylinders
C-6	Standards for Visual Inspec. of Steel Compressed Gas Cylinders
C-6.1	Standards for Visual Inspec. of High Pressure Aluminum Compressed Gas Cylinders
C-6.2	Guidelines for Visual Inspec. & Requalification of Fiber Reinforced High Pressure Cylinders
C-6.3	Guidelines for Visual Inspec. & Requal. of Low Pressure Aluminum Compressed Gas Cylinders
C-7	Guide to the Preparation of Precautionary Labeling & Marking of Compressed Gas Containers
C-8	Standard for Requal .of DOT-3HT Seamless Steel Cylinders
C-9	Standard Color-Marking of Compressed Gas Cylinders Intended for Medical Use
C-10	Recomm. Procedures for Changes of Gas Service for Compressed Gas Cylinders
C-11	Recomm. Practices for Inspection of Compressed Gas Cylinders at time of Manufacture
C-12	Qualification Procedure for Acetylene Cylinder Design
C-13	Guidelines for Periodic Visual Inspec. & Requal. of Acetylene Cylinders
C-14	Procedures for Testing DOT Cylinder/Safety Relief Device Systems
C-15	Procedures for Cylinder Design Proof & Service Performance Tests
C-16	Registration Program for Cylinder Owner Symbols & Company Names
CGA341	Standard for Insulated Cargo Tank Specification for Cryogenic Liquids
E-1	Standard Connections for Regulator Outlets, Torches for Compressed Gases Welding & Cutting Equip
E-2	Hose Line Check Valve Standards for Welding & Cutting
E-3	Pipeline Regulator Inlet Connection Standards
E-4	Standard for Gas Regulators
E-5	Torch Standard for Welding and Cutting
E-6	Standard for Hydraulic Type Pipeline Protective Devices
E-7	ANSI for Medical Gas Regulators & Flowmeters
E-9	Standard for Medium Pressure (3000 PSIG) Flexible P.T.F.E.-Lined Pigtails for Compressed Gas Service
G-1	Acetylene
G-1.1	Commodity Specification for Acetylene
G-1.2	Recommendations for Chemical Acetylene Metering
G-1.3	Acetylene Transmission for Chemical Synthesis
G-1.5	Carbibe Lime - Its Value and Its Uses
G-1.6	Recomm, Practices for Mobile Acetylene Trailer Systems
G-1.7	Standard for Storage & Handling of Calcuim Carbine in Containers
G-2	Anhydrous Ammonia
G-2.1	ANSI Safety Requirements for the Storage and Handling of Anhydrous Ammonia; ANSI K61.1
G-2.2	Guideline Method of Determining Minimum of 0.2% Water in Anhydrous Ammonia
G-3	Sulfur Dioxide
G-4	Oxygen
G-4.1	Cleaning Equipment for Oxygen Service
G-4.3	Commodity Specification for Oxygen
G-4.4	Industrial Practices for Gaseous Oxygen Transmission & Distribution Piping and Systems
G-4.5	Commodity Specification for Oxygen Produced by Chemical Reaction
G-4.6	Oxygen Compressor Installation Guide
G-4.8	Safe Use of Aluminum Structured Packing for Oxygen Distillation
G-5	Hydrogen
G-5.3	Commodity Specification for Hydrogen
G-5.4	Standard for Hydrogen Piping at Consumer Locations
G-6	Carbon Dioxide
G-6.1	Standard for Low Pressure Carbon Dioxide Systems at Consumer Sites
G-6.2	Commodity Specification for Carbon Dioxide
G-6.3	Carbon Dioxide Cylinder Filling & Handling Procedures
G-6.4	Safe Transfer of Low Pressure Liquefied Carbon Dioxide in Cargo Tanks, Tank Cars, & Portable Containers
G-6.5	Standard for Small Stationary Low Pressure Carbon Dioxide Systems
G-6.6	Standard for Elastomer-Type Carbon Dioxide Bulk Transfer Hose
G-7	Compressed Air for Human Respiration
G-7.1	ANSI Commodity Specification for Air
G-8.1	Standard for Nitrous Oxide Systems at Consumer Sites
G-8.2	Commodity Specification for Nitrous Oxide
G-9.1	Commodity Specification for Helium
G-10.1	Commodity Specification for Nitrogen
G-11.1	Commodity Specification for Argon
G-12	Hydrogen Sulfide
HB-3	Handbook of Compressed Gases
P-1	Safe Handling of Compressed Gases in Containers
P-2	Charac. & Safe Handling of Medical Gases
P-2.5	Transfilling of High Pressure Gaseous Oxygen to be Used for Respiration
P-2.6	Transfilling of Liquid Oxygen to be Used for Respiration
P-2.7	Guide for the Safe Storage, Handling & Use of Portable Liquid Oxygen System ins Health Care Facilities
P-5	Suggestions for the Care of High-Pressure Air Cylinders for Underwater Breathing
P-6	Standard Density Data, Atmospheric Gases & Hydrocarbons
P-7	Standard for Requal. of Cargo Tank Hose Used in the transfer of Compressed Gases
P-8	Safe Practices Guide for Air Separation Plants
P-9	The Inert Gases - Argon, Nitrogen and Helium
P-10	Standard for Vinyl Chloride Monomer Tank Car Manway Cover and Protective Housing Arrangement and Emergency Safety Kit
P-11	Metric Practice Guide for Compressed Gas Industry
P-12	Safe Handling of Cryogenic Liquids
P-13	Safe Handling of Liquid Carbon Monoxide
P-14	Accident Prevention in Oxygen-Rich & Oxygen-Deficient Atmospheres
P-15	Filling of Industrial & Medical Nonflammable Compressed Gas Cylinders
P-16	Recomm. Procedures for Nitrogen Purging of Tank Cars
P-17	Procedures for Pneumatic Retesting of Cargo & Portable Tanks
P-18	Standard for Bulk Inert Gas Systems at Consumer Sites
P-19	Hazard Ratings for Compressed Gases
P-20	Standard for the Classification of Toxic Gas Mixtures
P-21	Guidelines for the Development of Pre-Trip Inspec. Check List & reports for MC 338/TC 338 & TC 341 Cargo Tanks
P-22	The Responsible Management & Disposition of Compressed Gases & Their Containers
P-23	Standard for Categorizing Gas Mixtures Containing Flammable and Nonflammable Components
P-24	Guide to the Preparation of Material Data Safety Sheets
S-1.1	Pressure Relief Device Standards - Part 1 - Cylinders & Fitted Hose for Compressed Gases
S-1.2	Pressure Relief Device Standards - Part 2 - Cargo and Portable Tanks for Compressed Gases
S-1.3	Pressure Relief Device Standards - Part 3 - Compressed Gas Storage Containers
SB-1	Hazards of Refilling Compressed Refrigerant(Halogenated Hydrocarbon) Gas Cylinders
SB-2	Oxygen-Deficient Atmospheres
SB-4	Handling Acetylene Cylinders in Fire Situations
SB-5	Hazards of Reusing Disposable Refrigerant (Halogenated Hydrocarbon) Gas Cylinders
SB-6	Nitrous Oxide Security and Control
SB-7	Rupture of Oxygen Cylinders in the Diving Industry
SB-8	Use of Oxy-Fuel Gas Welding and Cutting Apparatus
SB-9	Recomm. Practice for the Outfitting and Operation of Vehicles Used in the Transportation and Transfilling of Liquid Oxygen to be Used for Respiration
SB-10	Correct Labeling & Proper Fittings on Cylinders/Containers
SB-11	Use of Rubber Welding Hose
SB-12	Use of Regulator Pressure Gauges
SB-13	Use of regulators on Compressed Gas Cylinders over 3000 psig
SB-14	Helium Gas for Filling Balloons
SB-15	Avoiding Hazards in Confined Work Spaces During Maintenance, Construction, & Similar Activities
SB-16	Use of High Flow Oxy-Fuel Gas Heating Torch Apparatus
SB-18	Use of Refrigerant (Halogenated Hydrocarbons) Recovery Cylinders
TB-2	Guidelines for Inspection and Repair of MC-330 and MC-331 Anhydrous Ammonia Cargo Tanks
TB-3	Hose Line Flashback Arrestors
TB-4	Certification for Exchange Product or Customer Pickup of Bulk Medical Liquids
TB-8	Evidence of Ownership of Compressed Gas Cylinders
TB-8.1	Poster Version
TB-9	Guidelines for the Proper Handling & Use of the CGA 630/710 Series "Ultra High Integrity Service" Connections
TB-10	Method of Calculating the Acceptable Level of an Impurity in Carbon Dioxide for Carbonated Beverage Applications
TB-11	Sulfur Dioxide tank Truck (Cargo Tank) Connections
V-1	CGA Standard for Compressed Gas Cylinder Valve Outlet & Inlet Connections
V-5	Diameter-Index Safety System
V-6	Standard Cryogenic Liquid Transfer Connections
V-6.1	Standard Carbon Dioxide Transfer Connections
V-7	Standard Method of Determining Cylinder Valve Outlet Connections for Industrial Gas Mixtures
V-9	ANSI, CGA Standard for Compressed Gas Cylinder Valves

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FAQ

Date: January 03

Subject: Size E Oxygen Cylinders

Effective immediately, the JCAHO is referencing Chapter 9 of the 2002 edition of NFPA 99, Healthcare Facilities regarding the storage of compressed gas cylinders outside of fire protected areas. No more than 300 cubic feet of nonflammable compressed gases that are determined necessary for immediate use may be stored in a single unprotected area.

Because the average size "E" cylinder contains 25 cubic feet of gas, no more than 12 size "E" cylinders may be stored in the same unprotected area. Also, since the average size "H" cylinder contains 250 cubic feet of gas, no more than one "H" cylinder and two size "E" cylinders may be stored in the same unprotected area.

MEDICAL GAS MANAGEMENT, INC.

MEDICAL GAS SYSTEM
CERTIFICATION TESTING

The following systems have been inspected and tested for certification. Items not complying to applicable standards are described in the comments section of this report. These Medical Gas and Vacuum Systems have been inspected, tested and are certified to ANSI/NFPA 99,_____.

1. SYSTEMS TESTED	CERTIFIABLE		
A. Oxygen	[ ] YES	[ ] NO	[ ] N/A
B. Medical Air	[ ] YES	[ ] NO	[ ] N/A
C. Nitrous Oxide	[ ] YES	[ ] NO	[ ] N/A
D. Nitrogen	[ ] YES	[ ] NO	[ ] N/A
E. Vacuum	[ ] YES	[ ] NO	[ ] N/A
F. Carbon Dioxide	[ ] YES	[ ] NO	[ ] N/A
G. EVAC	[ ] YES	[ ] NO	[ ] N/A

2. INSPECTION AND TESTS CONDUCTED			
A. Qualification of Installer	[ ] PASS	[ ] FAIL	[ ] N/A
B. Brazing Performance	[ ] PASS	[ ] FAIL	[ ] N/A
C. Materials	[ ] PASS	[ ] FAIL	[ ] N/A
D. Installation Procedures	[ ] PASS	[ ] FAIL	[ ] N/A
E. 150 PSIG Pressure Test	[ ] PASS	[ ] FAIL	[ ] N/A
F. 24 Hour Standing Pressure Test	[ ] PASS	[ ] FAIL	[ ] N/A
G. Crossed Line Test	[ ] PASS	[ ] FAIL	[ ] N/A
H. Identification Inspection (Alarms, Valves, Outlets, Pipe)	[ ] PASS	[ ] FAIL	[ ] N/A
I. Blowdown Test (White Cloth)	[ ] PASS	[ ] FAIL	[ ] N/A
J. Valve Operation Test	[ ] PASS	[ ] FAIL	[ ] N/A
K. Alarm Test	[ ] PASS	[ ] FAIL	[ ] N/A
L. Flow Test	[ ] PASS	[ ] FAIL	[ ] N/A
M. Operational Pressure Test	[ ] PASS	[ ] FAIL	[ ] N/A
N. Medical Gas Concentration Test	[ ] PASS	[ ] FAIL	[ ] N/A
O. Existing System Particulate Test	[ ] PASS	[ ] FAIL	[ ] N/A
P. Piping Purity Test (Particulate/Gaseous)	[ ] PASS	[ ] FAIL	[ ] N/A
Q. Final Tie-In Test	[ ] PASS	[ ] FAIL	[ ] N/A

3. SOURCE EQUIPMENT			
A. Oxygen	[ ] PASS	[ ] FAIL	[ ] N/A
B. Medical Air	[ ] PASS	[ ] FAIL	[ ] N/A
C. Nitrous Oxide	[ ] PASS	[ ] FAIL	[ ] N/A
D. Vacuum	[ ] PASS	[ ] FAIL	[ ] N/A
E. Nitrogen	[ ] PASS	[ ] FAIL	[ ] N/A
F. Carbon Dioxide	[ ] PASS	[ ] FAIL	[ ] N/A
G. EVAC	[ ] PASS	[ ] FAIL	[ ] N/A

DATE:_____ Job Number:_____

Technician:_____

Medical Gas and Vacuum Systems

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Chapter Five

Keeping the System "Up" and Maintaining Peak Performance

It is not only important to verify and certify the performance of a medical gas system after installation or modification, but it is also essential to ensure that the system continues to function as designed and intended. Not only will total operating costs be reduced with an effective preventive maintenance program (due to reductions in unanticipated breakdowns and early component failures), but also potential liability will be reduced if a quality assurance and performance testing program is also in place.

Compliance with certain regulatory agencies is necessary to achieve accreditation and to meet local, state, and federal laws. Many medical facilities are members of the Joint Commission on the Accreditation of Healthcare Organizations, which requires that "there is a utilities management program designed to ensure the operational reliability, assess the special risks, and respond to failures of utility systems that support the patient care environment." This implies that the medical gas system components must be tested on a regular basis and that the results must be documented, personnel must be trained, and policies and procedures must be developed and followed.

Preventive Maintenance

In designing a preventive maintenance program, it is important to consider the following steps:

1. *Inventory*—The first step is to determine what equipment must be maintained. For medical gas and vacuum systems, this includes the storage tanks, manifolds, shutoff valves, alarm systems, connectors, pumps, and other miscellaneous units. Every item that will need preventive maintenance should be included in the inventory.
2. *System Layouts*—"As-built" drawings should be obtained or created that accurately reflect the current medical gas and vacuum system. These drawings should clearly identify where each of the components are located, such as shutoff valves and alarm panels. Color coding or symbolic labels are frequently used and are an effective way to quickly locate specific items in emergencies. Because architectural blueprints are often combined with other floor plan and structural details, it is recommended that separate layouts be drawn that are uncluttered and show only the necessary system components.
3. *Equipment Evaluation*—After each system component has been located, identified, and inventoried, an evaluation of the equipment status must be completed. The condition of the system devices will probably vary widely, and equipment in need of immediate maintenance will have to be noted and repaired. The condition of each piece of equipment is also important when determining the intervals for preventive maintenance. Components that are subject to frequent use or harsh conditions, or are of poor design, will require more frequent attention than those that are rarely used or have historically been trouble-free. This evaluation of equipment should also include an estimate of remaining useful life so that long-range plans for equipment replacement can be made.

4. *Policies and Procedures*—When the equipment list has been compiled and the system components have been evaluated, the policies and procedures for maintaining the medical gas and vacuum system should be written down. Consideration should be given to the cost-benefit relationships (for example, how much will have to be spent to extend the system life an additional 20 years?), manpower, and available and existing local, regional, state, and federal codes and guidelines. Most facilities choose to follow minimum requirements, although frequently this is not the best long-term solution, even from a financial perspective. In addition, policies must not only address the equipment maintenance and "up time," but also must consider patient and staff safety and potential liability. Therefore, all policies should be reviewed and approved by the hospital administrative staff as well as the safety and risk management committees. The procedures should be written so that they are easy to follow by the employees who will be performing the maintenance. Usually, a work order card is distributed to the maintenance worker that lists the step-by-step tasks necessary to complete the maintenance work. Often, the card lists the procedures that must be followed and also indicates the necessary tasks, materials, and time required to perform the job.
5. *Performing the Work*—It is important that each of the maintenance workers understand the critical nature of performing preventive maintenance or repair on medical gas and vacuum systems. If a section of the system is to be turned off, double-checks must be made to verify that other areas are not affected. Advance warning must be given to all of the affected departments so that there is sufficient time to prepare for the outage. Back-up oxygen, nitrous oxide, and medical air tanks must be available for use as well as extra vacuum pumps in case they are needed. If necessary, additional personnel should also be scheduled.
6. *Documentation*—It is not sufficient to merely keep a current inventory of medical gas and vacuum components and test and maintain the system. Records must also document that the system has been tested, preventive maintenance has been performed, and repairs have been completed, when necessary. Whether these records are kept in file folders, storage boxes, or on computer disks, they must be readily available for review purposes (see appendix C for sample test documentation forms).
7. *Evaluating the Results*—The final step in an effective preventive maintenance program requires periodic, scheduled review of the work that has been performed. The following questions must be answered:

   Has all of the intended work been completed?
   Is the quality of work adequate?
   Was the work completed in a timely and efficient manner?
   Do the preventive maintenance test results indicate that changes need to be made in the policies, procedures, or frequency of tests?

To answer these questions, quality assurance (QA) indicators can be used with target goals established for measurement purposes. Some sample QA indicators and goals are listed in figure 5-1.

Figure 5-1. QA Indicators for Preventive Maintenance

Function	Indicator	Goal
Completion of work	PM tests completed ÷ PM tests scheduled	≥ 90%
Quality of work	% Sample of Completed Documentation	—
Timeliness/Efficiency	Actual Hours ÷ Scheduled Hours	< 1.0
Program Changes	Mean Time Between Failures/Callbacks	—

Preventive Maintenance Program

Some of the most frequently asked questions concerning preventive maintenance include the following:

- What medical gas and vacuum equipment should be included in the maintenance inventory?
- What tests should be performed to comply with applicable codes and standards and how often should they be performed?

The answer to the first question is straightforward—include any piece of equipment on the maintenance inventory that requires preventive maintenance, needs periodic attention such as cleaning or repair, or is considered a capital asset. Also, be sure to include equipment that may play a role in life support, infection control, or environmental support systems. In summary, include any items that affect patient care. Whether equipment maintenance is the responsibility of the in-house department or provided through a service contract, there should be an in-house inventory list to account for it.

The answer to the second question varies widely, and depends on local requirements, requests by the insurance carrier for the hospital, and decisions made by the hospital administrative staff based on resources available to the maintenance department. As a guideline, figure 5-2 lists typical equipment that is part of a medical gas and vacuum system and describes which preventive maintenance tests should be performed at the recommended test interval. For reference purposes, applicable codes, standards, and regulations are also listed. (For additional information, refer to appendix B, Sample Preventive Maintenance Procedures.)

Personnel Training

Whether or not in-house staff are utilized to perform all of the testing, preventive maintenance, and repair functions for the medical gas and vacuum systems, a certain minimum level of training is necessary for hospital maintenance employees and other selected staff members. The *1989 JCAHO Accreditation Manual* requires that "utility system operational plans are written to . . . train users and operators of the system." In addition, "orientation and at least annual continuing education for individuals who use and/or maintain utility systems are documented." This specifies that personnel who operate or maintain the medical gas system must be familiar with the system operation, know where shutoff valves and master and area alarm panels are located, and be knowledgeable about procedures during emergencies. It is also necessary to keep accurate records of employee participation in training programs.

Figure 5-3 provides a list of training recommendations for personnel within the hospital.

System Repair

Regardless of how a medical gas and vacuum system is maintained, some repairs will ultimately have to be made. Typical problems may include pressure switch malfunctions on alarm panels, mechanical breakdowns and leaks on outlets and hoses, gaskets, seals, and couplings that begin to leak, compressor and pump failures, and control panel malfunctions. When repairs are necessary, the following steps should be followed:

1. *Inform users about the malfunction and the intended repairs.* Because medical gas systems are critical to the proper treatment of patients, staff must be fully informed whenever a problem occurs. Be sure to communicate how long the repair is expected to take and what patient care area will be affected.
2. *Complete all arrangements for "back-up support."* Prior to the initiation of repairs, ensure that adequate resources for back-up have been provided. If portions of the system will be turned off, make sure that sufficient portable tanks, vacuum pumps, and extra personnel are available when needed.

Figure 5-2. Guidelines for Medical Gas and Vacuum System Preventive Maintenance

Component Description	Preventive Maintenance Task	Recommended Frequency	*Reference
NFPA Recommendations			
Bulk System			
Bulk supply cylinder systems w/o reserve supply	Visual check of system pressure and changeover status	Daily	NFPA99, C-4.2.1
Bulk supply cylinder systems with reserve supply	Visual check of system pressure and changeover status	Daily	NFPA99, C-4.2.2
Bulk reserve supply contents activating switch	Check proper activating switch function	Annually	NFPA99, C-4.2.3
Bulk system supply	Check tank contents	Daily	NFPA99, C-4.2.4
Bulk system master signal panel	Operational checks of the signal panel system	Periodic	NFPA99, C-4.2.5
Mainline pressure gauges	Pressure within acceptable limits	Daily	NFPA99, C-4.2.6
Medical Air Compressor Components			
Medical Air compressor air intake	Location check for satisfactory placement	Quarterly	NFPA99, C-4.2.8
Pressure gauge	Pressure within acceptable limits	Annually	NFPA99, C-4.2.7
Water level sensor	Sensor operation	Annually	NFPA99, C-4.2.7
Receiver drain	Water accumulation	Daily	NFPA99, C-4.2.7
Air compressor (reciprocating)	Mechanical tests	Manufacturer specifications	NFPA99, C-4.2.8
Absorber beds	Water saturation check	Manufacturer specifications	NFPA99, C-4.2.8
System dew point sensor	Check for proper operation	Annually	NFPA99, C-4.2.8
System instrumentation	Calibration and proper operation	Routinely	NFPA99, C-4.2.8
Air system alarms	Functional tests	Annually	NFPA99, C-4.2.13
Alarm System Components			
Signal alarm panels	Pressure alarm test buttons audible and visual signals	Monthly	NFPA99, C-4.2.9
Warning system components	Functional tests	Annually	NFPA99, C-4.2.14
Pressure gauges at master and area alarms	Proper system pressure	Daily	NFPA99, C-4.2.14
Manifold Supply Systems			
Reserve-in-use and supply low warning system	Test proper function	Annually	NFPA99, C-4.2.11
Reserve-in-use and supply low warning system	Test audible and visual signals	Monthly	NFPA99, C-4.2.11, C-4.2.12
System Peripheral Devices			
Shut off valves	Leakage test	Periodically (Annually)	NFPA99, C-4.2.18
Station outlets	Proper flow and leakage	Periodically (Annually)	NFPA99, C-4.2.19
Canadian Standards Recommendations			
Outlets	Function, wear, mechanical performance, leak test	Annually	CSAZ305.1;14.3
Shutoff valves	External leakage, shutoff "tightness"	Annually	CSAZ305.1;14.2.1.d

Alarms	Function test	Semi-annually	CSAZ305.1.14.2.1c
	Line pressure observation	Daily, each shift	CSAZ305.1.14.2.1a
Regulators	Pressure relief test	Annually	CSAZ305.1.14.2.1b
Relief valves	Transfer from:	Semi-annually	CSAZ305.1.14.1.1
Bulk gas supply	1. Primary to secondary		
	2. Secondary to reserve		
	3. Primary to Reserve		CSAZ305.1.14.1.2a
Manifold system	1. Regulator leaks	Semi-annually	CSAZ305.1.14.1.2b
	2. Cylinder pigtail leak check valve closure	Semi-annually	CSAZ305.1.14.1.2c
	3. Cylinder extension lead flexibility, metal fatigue, thread damage	Semi-annually	CSAZ305.1.14.1.2c
	4. Leaks and closure ability of manifold hand valves		CSAZ305.1.14.1.3
Nitrous oxide supply tanks	Observe cylinders for evidence of surface frosting or condensation during peak use (Indicates leaks)	Daily	
Air compressor/vacuum pump	1. Function of automatic alternating controls	Weekly	CSAZ305.1.14.1.4a1
	2. Correct pressure/vacuum switch	Weekly	CSAZ305.1.14.1.4a3
	3. Frequency of pump starts and run period duration	Weekly	CSAZ305.1.14.1.4a3
	4. Cut-in and cut-out pressure	Weekly	CSAZ305.1.14.1.4a4
	5. Proper water flow to aftercooler	Weekly	CSAZ305.1.14.1.4a5
	6. Proper operation on automatic drain for receivers and dryers	Weekly	CSAZ305.1.14.1.4a6
	7. Proper operation of refrigerator dryer	Weekly	CSAZ305.1.14.1.4a7
	8. Pressure check across filters	Weekly	CSAZ305.1.14.1.4b
Each medical gas system	1. One-hour standing pressure test	5 years	CSAZ305.1.14.4
	2. Purity at randomly selected outlet	Annually	CSAZ305.1.14.5
Medical Air Proportioners	Accuracy check	Weekly	CSAZ305.1.14.1.5
ECRI Recommendations			ECRI Feb. 1987
Area pressure alarms	Test for alarm activation, audible and visual alarm indication, and gauge accuracy	Annually	ECRI Feb. 1987
Zone valves	Check for correct labeling and operation	Annually	
Gas outlets	Check condition, label, coverplate, color coding, adapter operation, static pressure, gas concentration, connecting hoses	Annually	ECRI Feb. 1987
Vacuum outlets	Condition of each outlet, labeling, vacuum and flow	Annually	ECRI Feb. 1987

continued on next page

Figure 5-2. Continued

Component Description	Preventive Maintenance Task	Recommended Frequency	*Reference
ECRI Recommendations (continued)			
Meter alarm panel	Operational tests	Annually	ECRI Feb. 1987
Medical gas analysis	Dewpoint tests, impurity levels	Annually	ECRI Feb. 1987
Compressed Gas Association Recommendations			
Bulk Nitrous Oxide Systems	1. Inspection and maintenance by qualified personnel	Annually	CGA G-8.1,15.1
	2. Removal of combustibles within 15' of N_2O storage container	As required	CGA G-8.1,15.2
NFPA Recommendations			
Bulk Oxygen Systems	1. Inspection and maintenance by qualified personnel	Annually	NFPA 50, 4-2.1
	2. Cut back weeds and long grass within 15 feet of any bulk oxygen storage container	As required	NFPA 50, 4-2.2
JCAHO Recommendations			
Total medical gas system	A program of preventive maintenance and periodic inspection must be in place to ensure safe and reliable operation	As necessary to maintain a safe and reliable system	JCAHO, 1989 PLAN 1
Total medical/surgical vacuum	A program of preventive maintenance and periodic inspection must be in place to ensure safe and reliable operation	As necessary to maintain a safe and reliable system	JCAHO, 1989 PL 4.4.1

*Abbreviations for the following documents are listed below:
NFPA 99: *Healthcare Facilities*, 1987 edition, National Fire Protection Association, Batterymarch Park, MA
CSAZ305.1-M1984, *Nonflammable Medical Gas Piping Systems*, Canadian Standards Association, Rexdale, Ontario, Canada
ECRI: *ECRI Health Devices*, February 1987, Inspection and Preventive Maintenance Procedure: Medical Gas/Vacuum Systems, Philadelphia
GCA G-8.1: *Standard for Nitrous Oxide Systems at Consumer Sites*, 1979, Compressed Gas Association, New York City
NFPA 50: *Standard for Bulk Oxygen Systems at Consumer Sites*, 1979, National Fire Protection Association, Batterymarch Park, MA
JCAHO: *Accreditation Manual for Hospitals*, 1989, Joint Commission for the Accreditation of Healthcare Organizations, Chicago

Contamination is another potential problem, although it is not likely to occur with oxygen or nitrous oxide lines unless improper system installation techniques or poor quality materials have been used. Contamination of the medical air system is much more common and can occur when compressor seals fail or older style compressors are used that have been lubricated with oil-based compounds. Also, because air intakes for the medical air system can be improperly located, diesel fumes or contaminated air can enter and degrade the compressed air. To prevent these problems, thorough preventive maintenance should be performed on the compressor with particular attention provided to seals, fittings, and proper lubrication. Periodic contamination tests are also recommended with emphasis given to the amount of carbon monoxide present. (See figures 4-6 and 4-7 for gas purity requirements.) Massive system failures will occur if the normal and emergency power systems are not operational, such as during an internal disaster, and contingency plans must be in place to prepare for this possibility. Spare oxygen and nitrous tanks mounted on wheeled carriers with pressure regulators attached must always be available. Anesthesia equipment must always have oxygen and nitrous oxide tanks mounted to the side or rear yoke assembly of the machine and they should be tested periodically for proper function. A summary of medical gas and vacuum system equipment failures is provided in figure 6-2.

Compliance with Regulatory Agencies

The primary purpose for scheduling preventive maintenance and periodic testing on medical gas and vacuum systems and developing emergency policies and procedures in the event of system failure is to maximize safety and improve the quality of patient care. At the same time, it is important to minimize the risk of accidents, liability exposure, and financial loss. Although it may seem that regulatory agencies require compliance with unreasonable directives that consume scarce financial resources, some hospital administrators stress the importance of these regulations *after* they have been involved in a medical gas system incident—that could (and should) have been prevented. Even though some health care administrators are of the opinion that many regulations are endless, redundant, and unnecessary, most

Figure 6-2. Medical Gas and Vacuum System Problems Related to Equipment Failure

System Component	Problem	Recommended Solution
Bulk tank secondary and reserve supplies	Panel failure, gas empty without alarm indication	Daily pressure checks, preventive maintenance on bulk tank high pressure system
Master and area alarms	Alarm failure, system pressure drop without audible warning	Daily system pressure checks, preventive maintenance on area and master alarm system
System shutoff valves	Valve not operational	Periodic preventive maintenance, accurate chart of other "up-line" and "down-line" valve locations
System pipelines	Line to line contamination due to check valve failure	Keep oxygen line pressure higher than medical air; keep medical air pressure higher than nitrous oxide. Check line purity periodically.
Medical air compressor	Compressor failure contamination	Preventive maintenance on vacuum system, portable back-up vacuum pumps available
All system components	Normal and emergency power failure	Portable tanks with regulators available as back-up, internal disaster policy in place

standards are voluntary. Figure 6-3 lists agencies and organizations that are currently involved in regulating the proper use of medical gases (note that in the "Compliance Requirement" column of the table, enforcement of many of the standards is dependent on state or local agencies). Typically, hospitals need to be concerned only with the regulations published by the NFPA, especially if they have been adopted by their local governing authority. They might also need to comply with recommendations from the Joint Commission or the American Osteopathic Association (AOA), if they are seeking accreditation by either of these voluntary organizations.

Because compliance with the NFPA and the Joint Commission will satisfy the requirements for most hospitals and will result in a low-risk, well-managed program, a systematic review of the requirements and their explanation is given as follows. (Note that this review provides general features of the requirements only. For specific information about each requirement, refer to the sections in the indicated publication.)

Figure 6-3. Applicable Codes and Requirements

Jurisdiction	Agency	Compliance Requirement	Description of Requirements
Federal	U.S. Department of Transportation (DOT)	Required	Regulates the construction, testing, and maintenance of gas cylinders. Little impact on gas system *users*.
Federal	Occupational Safety and Health Administration (OSHA)	Required	Permits federal inspections by OSHA representatives when facilities use or store medical gases. Usually of consequence after an accident has occurred or when a complaint is filed.
Federal	Food and Drug Administration (FDA)	Required	Controls and regulates the shipment of medical gases (in interstate commerce) and enforces standards published by the United States Pharmacopeial Convention (USP). Little impact on gas system *users*.
Federal	Department of Health and Human Services (HHS)	As adopted by federal, state, or local agencies	Recommended guidelines for medical gas and vacuum system installation in new medical facilities only.
None	National Fire Protection Association (NFPA)	As adopted by federal, state, or local agencies	Publishes recommended standards for the design, installation, testing, and maintenance of medical gas and vacuum systems.
None	Compressed Gas Association (CGA)	As adopted by federal, state, or local agencies	Develops and publishes safe methods for handling, storing, and using medical gases.
None	Joint Commission for the Accreditation of Healthcare Organizations (JCAHO)	Required for institutions seeking JCAHO accreditation	Requires documented preventive maintenance and training programs for medical gas and vacuum systems.
None	American Osteopathic Association (AOA)	Required by institutions seeking AOA accreditation	Documented equipment preventive maintenance and repair program is necessary.

Appendix E
Qualification Requirements for Gas Testing and Certification Companies

The following guidelines are intended to help in the selection of companies that are qualified to perform medical gas and vacuum system certification tests. Although these recommendations are not required by any regulatory agency in the United States, their use can result in a safer installation. For additional information concerning qualification requirements, refer to publication CAN3-Z305.4-M85, which is available from the Canadian Standards Association.

When contracting a company to perform medical gas certification, request that the following information be provided in its proposal:

CORPORATE INFORMATION TO BE REQUIRED

1. The name and address of the office(s) that will be responsible for the testing
2. The date of incorporation of the company
3. The extent of the services that the company provides
4. The number of similar certification tests that have been performed during the past year
5. Representative clients who have contracted with the company for gas certification during the past year.
6. A copy of any licenses, permits, or authorizations issued by any governmental authorities to perform the services
7. A copy of the insurance binder to verify the purchase of professional liability insurance (errors, omissions, and completed operations—not just general liability)

QUALIFICATIONS OF COMPANY EMPLOYEES TO BE PROVIDED

1. A summary of the credentials of the field representatives who will be performing the tests, their supervisor, and the engineer who will be certifying the results (because the medical gas test results can affect the public health, the certifying engineer should be registered to practice professional engineering in the applicable state(s))
2. Evidence of sufficient training and experience in medical gas testing for the field representatives, supervisor, and certifying engineer

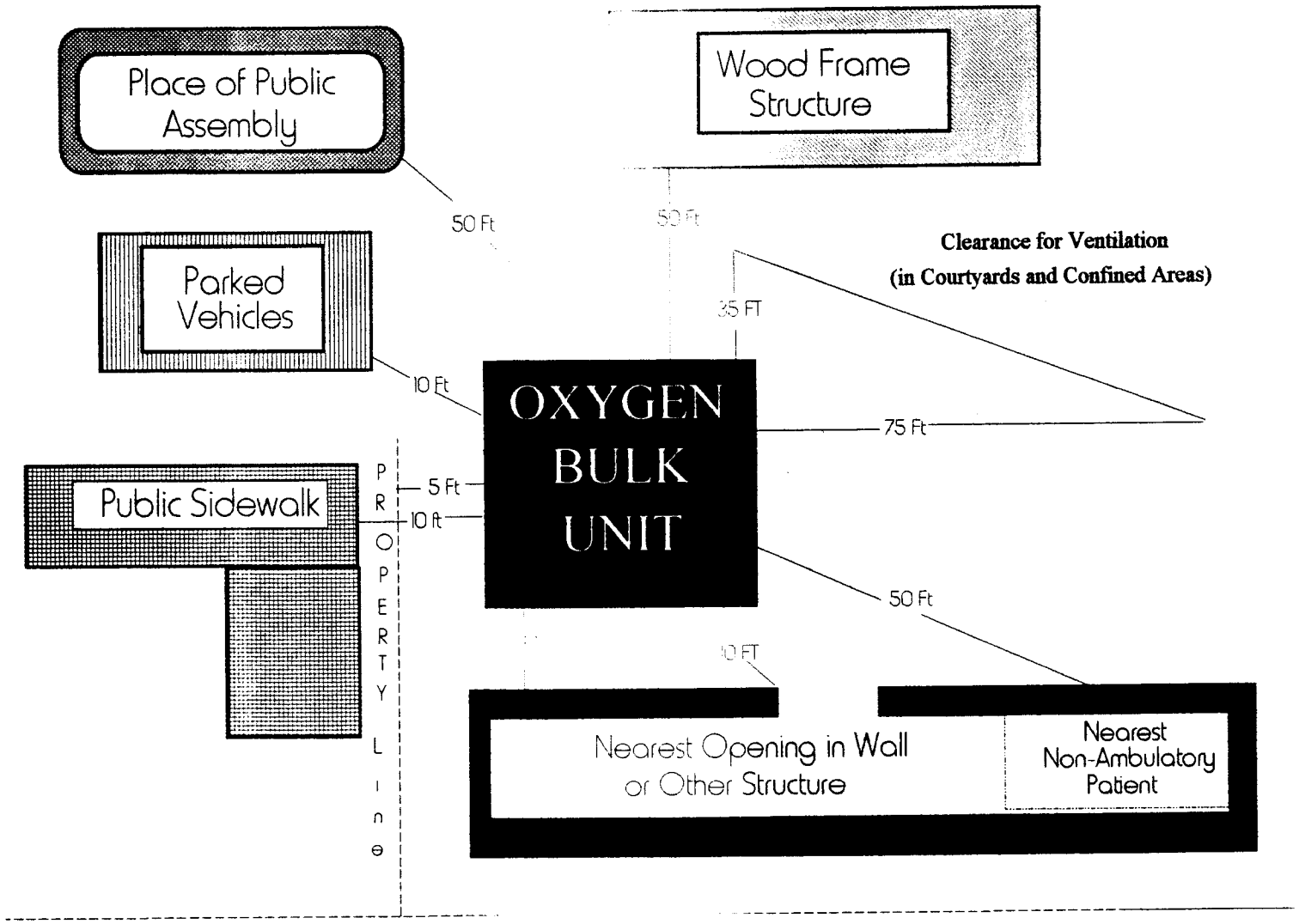
TESTING PROCEDURE TO BE PROVIDED

1. The test procedures to be followed
2. A list of the test equipment to be used during the testing and its measurement accuracies and calibration data
3. Names of testing laboratories that will, if necessary, perform additional analytical services

DOCUMENTATION TO BE PROVIDED

1. Sample forms used to record test results
2. Sample reports from previous certification test

DISTANCE BETWEEN BULK OXYGEN SYSTEMS AND EXPOSURES
Part one



Medical Gas Contamination
An Unrecognized Patient Danger

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MAR-S008

Medical Gas Contamination An Unrecognized Patient Danger

by Ervin Moss, M.D.

Anesthesia personnel usually automatically assume that the medical gases delivered from the wall outlets in the OR are clean, correct, and safe. While crossed-pipeline accidents always receive significant publicity, an under-appreciated patient safety issue concerns possible contamination of these medical gases with substances or materials that could possibly harm anesthesia equipment and, directly or indirectly, the patient breathing these gases.

Background

The original purpose of the APSF Subcommittee on Medical Gas Systems was to make anesthesiologists aware of the design, location, and problems of the life support system with which they work everyday, but which is beyond the walls and out of sight.

Coincidentally, the ECRI, a non-profit health services research agency, formerly the Emergency Care Research Institute, has devoted a special double issue (January-February 1994 vol. 23 No. 9 1-2) to medical gas and vacuum systems (MGVS). This publication should be in the library of every anesthesia department since it contains a crash course in what anesthesiologists should know about their MGVS. The address of ECRI is 5200 Butler Pike, Plymouth Meeting, PA 19462-1298.

ECRI correctly identified issues that this committee recognized early in its research. There is a mass of regulations, codes, and standards published by organizations such as the NFPA JCAHO, OSHA, CGA (Compressed Gas Institute), ANSI, AIA (American Institute of Architects), UL, and at least a dozen others. These regulations, standards, and codes address every aspect of the MGVS in hospitals and ambulatory care facilities from design to the concentration of agents used to clean pipes and valves. Why then are there reports of cross connections and contaminated pipes or why are fortunes needed or spent to correct errors in construction and design?

The ECRI, in its article, asked is there "a paper tiger" in all of these published regulations, standards, and codes? It discusses the "Problem in Enforcing Compliance" and "The Devil is in the Details." Even the JCAHO which updated its MGVS standards this year (*APSF Newsletter* Winter 93-94, Tom Nagle) "looks for evidence of a properly installed and routinely inspected MGVS only in the form of proper record keeping; it does not look for indepth adherence to the standard during on site visits...even insurers require that a MGVS meet certain tests and have documents pertaining to use and care...however, enforcement is lax and only documentation is required." ECRI further states that "although state and local building and fire codes may also regulate the construction and operation of MGVS and most state or local departments of health require certification of new installation before occupancy permits are issued...rigorous enforcement of the standard (NFPA) is spotty and depends on the interpretation of "authorities having jurisdiction" and the "responsible facility authority." Those authorities having jurisdiction "usually rely on information from independent inspectors or contractors, who may or may not be fully knowledgeable about the current details of NFPA-99 or even know how to perform complete testing of the MGVS...notably in the United States, no nationally recognized agency certifies MGVS inspectors as competent."

The article by ECRI confirms in no uncertain terms what the Committee on Medical Gas Systems of the APSF early identified and that is a lack of an accountable authority to coordinate and enforce the many codes and standards now in place. There should be an organizational chart with a specific agency at the top!

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Contaminated Gas Supply Is Underappreciated Patient Risk

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Included in the structure should be the education and credentialing of those involved in MGVS construction from design architects to plumbers. ECRI identified two private organizations involved in training of installers and verifiers, PIPE (Piping Industry Progress and Education Trust Fund, Los Angeles, California and Medical Gas Management, Bethany, Oklahoma). Mr. Fred Evans, President of MGM is a member of the APSF committee on Medical Gas Systems. Another organization cooperating with this committee is the American Medical Gas Institute, a non-profit organization, located in Metairie, Louisiana. There is a common frustration expressed by these companies in that they deal daily with the problems of faulty design, construction, installation, inspection, and certification, only to have deaf ears turned to them when recommendations to correct the faults to meet NFPA-99 standards are made to administrators.

California has strong MGVS construction requirements resulting from the Sylmar Earthquake of 1971. ECRI explains that "state law demands that MGVS adhere to the requirements of NFPA-99 as well as other codes defined by such agencies as AWS, CGA, ANSI, OSHA, and UL. Contractors must be certified as competent by recognized agencies such as AWS (American Welding Society), PIPE and ACIA (American Construction Inspection Association).

Inspect the Inspectors!

It is important that anesthesiologists understand that new construction may be inspected and certified by an individual who may not have himself or herself been credentialed for the task. It is not unusual for a facility to request certification just before opening its doors. Construction has been finished, the walls erected and the verifier (certifier) is limited to what he can see and do! Hidden behind the walls may be errors in design, incorrectly joined pipes which are improperly hung or supported and unclean. It is important not only to identify the gas flowing from each outlet, but to have an analysis of purity including particulate, chemical, and bacterial contamination. Logically, inspection of the MGVS should be continuously performed during each step of construction by credentialed inspectors and before the walls are put up. Certification should be by a disinterested third party as is required by Canadian Standards. It is not unusual for the contractor to be the certifier of his own work. Tennessee, through efforts of Mr. Fred Evans and Mr. Pete Winbourne, retired from Ohmeda, is in the process of requiring third party certification and MGVS regulations much like California has. Interestingly, Armed Forces facilities require certification by a third party.

Again, anesthesiologists must involve themselves during the construction phase of their MGVS. They must be knowledgeable as to the NFPA-99 codes. An excellent reference is the "Health Care Facilities Handbook" Fourth Edition published by the NFPA in which each code is explained in easy to understand terminology. Anesthesiologists should not hesitate to don a hardhat and enter the construction area. They are the end users of the MGVS and should understand the complexity of this life support system of their hospitals.

Anesthesiologists, during their workday, turn on gases and the vacuum systems with little thought as to the purity of the gases or the complexity of the MGVS. At the same time, in other units of the facility, gases are flowing to infants in incubators or on ventilators, or to patients in the ICU, CCU and even the Emergency Room. Suction is in use in all parts of the hospital. Although deaths are rare compared to the total number of patients using MGVS, when they do occur, the event gains nationwide attention and is followed by awards in the millions. In a ten year period one company, Medical Gas Services of Lenexa, Kansas, reported 205 instances of cross connection of which 81 involved a cross connection of a gas to the vacuum system. The excellent Canadian Standard is a result of 23 deaths in Sudbury, Ontario, in 1973 due to errors in construction of the MGVS.

81 Cases of Gas Pipelines Cross - Connected to Suction

California, according to PIPE, had as of December 1993, 368 certified inspectors and 22 certified verifiers as compared to many states that have none of either. California also hired an engineer to evaluate MGVS plans while in other states, approval of plans may be based on what the contractor tells the state.

Although there may be other organizations teaching and certifying installers, inspectors, and verifiers, the number is small. PIPE and MGM have training centers as well as the American Medical Gas Institute.

All three organizations offer programs in all parts of the United States. Although performing a vital service, they admit that they have developed their own curriculum and certification criteria and that there is no supreme body that sets educational standards as exists in our medical education system.

The worse possible scenario, other than crossed pipe lines, is an error by the manufacturer in the filling of tanks with the wrong gases at the manufacturing site. This possibility is responsible for the recommendation of the constant use of an oxygen analyzer on the machine even though an oximeter is in use. An oxygen monitor would have alarmed when a cylinder filled with nitrogen in error instead of oxygen was put on line. However, these monitors are not routinely used in other parts of the hospital. Therefore, it is important to understand the regulations placed on the manufacturer of the gas supply who incidentally are responsible for maintaining the bulk gas supply at hospitals.

When gas outlets are certified, the concentration or purity of the oxygen, nitrous oxide, nitrogen, or medical air is documented. What is not routinely identified is contaminants that may be present in acceptable or unacceptable levels. Particulate, foreign bodies, and bacteria are not the usual part of a certification of medical gases.

Included in the list of contaminants are metal fillings, flux, teflon, carbon, carbon oxide, oil and its breakdown products, halogenated solvents, methane, carbon monoxide, nitrogen oxide, hydrogen fluoride, hydrogen sulfate, carbon dioxide, cement, dirt, vermin, copper, copper oxide, copper carbonate, iron oxide, sand grains, wood chips, sodium crystals, chlorine, halogenated refrigerants, desiccant dust, fibers, aldehyde, lint, water and odor.

CO Monitored But Odor Banned

While there is an acceptable level for carbon monoxide (5PPM), and as of 1993 there must be a carbon monoxide monitor on the medical air system, there is no acceptable level for odor. Any odor originating from a medical gas system must be traced to its source. It is often the result of bacterial contamination or oil in the system. The medical air system, because of moisture, is the most common site of bacterial contamination. However, bacteria can grow in spaces left in improperly joined pipes. Culturing of medical gas is rarely performed. While ventilators and respiratory care systems are a known source of infection due to bacterial contamination, the idea that the source could be beyond the walls in the pipe systems is not easily accepted by owners or administrators possibly due to liability issues and the need to clean the systems once the contamination is identified.

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Debris, Water Pose Gas Pipeline Plugging Potential

Anesthesiologists Must Verify Gas System Works Perfectly

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Water that accumulates in medical air as a result of malfunctioning dryers can come out of air as dewpoint changes occur along the pipeline course. A dewpoint monitor and alarm is a part of a properly designed medical gas system. Remember, medical air is the result of compression of eight cubic feet of atmospheric air into one cubic foot of compressed air and that all contaminants in atmospheric air, including water and carbon monoxide, are therefore concentrated eight fold in compressed air.

The presence of iron or iron oxide (rust) is evidence of iron pipe being used against NFPA code somewhere in the MGVS. Once iron is documented after a nitrogen purge of a MGVS, a search should be made for the iron pipe. The iron pipe should then be removed and replaced by copper to meet the NFPA code requirements.

Multiple Contaminants!

Documented contamination of pipelines includes dirt, sand, gravel, cement, rust, vermin, cigarette butts, and wood. This form of contamination results from the pipes and bulk gas containers being opened and exposed to construction debris and to the atmosphere. NFPA code now requires all pipes to be clean and capped at the factory. The bulk gas system is delivered and installed by the gas supplier and may be on the construction site with ports open to the atmosphere. The anesthesiologist would be wise to check the bulk oxygen site and the condition of the containers during construction. The largest particulate recently found was a bird that had been sucked into a medical gas system as a result of faulty construction of the medical gas pipeline. Chemical contamination can be the result of solvents used by the manufacturer to clean pipes and valves.

The major form of particulate matter contamination is the result of improper joining (brazing) of pipes and joints during construction. Brazing should be performed by a certified brazer, but in reality may be performed by a plumber unaware of NFPA code that requires brazing be performed with the interior pipe purged with oil free nitrogen. When brazing is carried out in room air within the pipe, the oxygen content of the air can cause oxidation of the pipe at the temperatures required for brazing. The result is carbon, copper oxide, and carbon oxide.

Later, copper carbonate, recognized by its green color, is formed. All contaminants can scale off the interior of the pipe, flow downstream and impair the function of equipment such as flowmeters, outlets, ventilators, and blenders in ventilators.

The brazing must be carried out at 1000 degrees F using a special joiner specified by NFPA-99 code. Nitrogen purging must continue until the pipe is cooled to touch, otherwise oxidation will occur. This relatively simple procedure, first put into code in 1993, can prevent the major share of particulate contamination in MGVS. Yet, new construction completed in 1994 has found particulate contamination not meeting NFPA-99 standards. Although the NFPA-99 describes the brazing technique, the contractor may have given the job to a low bid plumber who is not acquainted with the code.

Examination of a pipe system for particulate matter involves a white cloth being placed over an outlet permitting gases to flow through the cloth. The cloth acts as a filter. The color, amount, and size of the particulate matter will determine the degree of contamination while identification of the particles and size can be made by microscopic examination.

Purging Needed

Cleaning of a pipe system can be performed by purging with nitrogen or washing. Purging will blow out loose scale and is temporary while washing with an acid solution can be a permanent solution, but is expensive and complex in that washing is performed zone by zone with shut down of zones during the process or may require the complete shutdown of the medical gas system.

Once again, the anesthesiologist should involve himself or herself in any new construction or addition to present systems. The credentials of the designers, contractors, installers and certification expert should be verified. Even the brazer should be credentialed.

Inspection should occur during the various phases of construction. Certification should be by a credentialed expert. Pipe lines should not only be certified for gas identification, but for contamination. It is hoped that more can be learned about bacterial contamination and its prevention and treatment.

Coming Attractions

In future articles the following topics will be discussed:

1. Gas shutdown of hospitals during construction or enlargement of the gas systems in a facility.

2. The problems and responsibility of bulk gas supply.

3. The medical air system.

4. Recent updates in NFPA code.

5. Important points to watch for, as an anesthesiologist, in design, construction, inspection, and verification of a medical gas system.

Dr. Moss of Verona, NJ, has been very active with and is a consultant to the New Jersey State Society of Anesthesiologists.

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Shutdown of Gas Supply Need Not Be Dangerous

Shutdown of Gas Supply System Need Not Be Danger

Planning Minimizes Risks

Editor's Note: This paper is one of a series on medical gas and vacuum systems to be printed in the *Newsletter*. Dr. Ervin Moss, a member of the Board of Directors of the Anesthesia Patient Safety Foundation and the chairman of the APSF Subcommittee on Medical Gas Vacuum Systems, is coordinating the series.

by Todd G. Peterson, MD, and Fred Evans, PhD

Anesthesia personnel in most operating room settings have come to rely on the Medical Gas Pipeline System (MGPS) as a dependable, very rarely interrupted supply of gases used in the delivery of anesthesia. Tanks are seldom used now except in the administration of anesthesia in places remote from the operating room or in the transportation of patients. As a consequence, anesthesia personnel often lack familiarity with backup plans when medical gas pipelines are shut down for periods of time longer than their machine mounted tank supplies would last. In a planned shutdown of the MGPS, whether for maintenance, modifications or repair, the Anesthesiology Department needs to actively participate throughout the process to assure the uninterrupted flow of gases necessary for safe patient care.

Stages Outlined

A planned shutdown of the MGPS involves three stages: the project definition and preparation prior to shutdown, the actual shutdown and modification of the MGPS, and the recertification of the system after repressurization. Key to minimizing downtime and risks to patients throughout this process are effective communication, preparation, and coordination between hospital departments and services affected by the shutdown and the contractor making modifications. Shutdowns without adequate communication among all those involved have resulted in near crisis situations and even some overt accidents.[1]

The planning process begins with a definition of the scope of the project and should ultimately produce a comprehensive, written shutdown procedure to accomplish the task. The planning process requires an up-to-date, accurate plan of MGPS as actually constructed. Despite the JCAHO requirement for hospitals to have this on file, it is not uncommon for the institution to only have the architect's original plans.[2] In this situation, a careful "hand over hand" tracing of the system to verify and update the drawings is indicated to prevent unexpected loss of gas supply, prevent construction errors, and minimize downtime. This is also a good time to have a consultant or the internal engineering department reevaluate the MGPS to verify that it continues to meet code requirements and initiate any indicated modifications.

The contractor uses the MGPS drawings to determine how extensive a shutdown is required, to accurately identify the areas affected during the shutdown, to locate valves required for shutdown, and to reasonably estimate downtime. The MGPS, if designed correctly, incorporates a series of shut-off and control valves which include:

1. The source valve - located externally directly downstream of the bulk source equipment.
2. The main shut-off valve - normally the first valve inside the facility.
3. Riser valves - located at the base of each riser in multistory buildings.
4. Floor valves - though not required, they are located at each branch off the riser and are used to isolate an entire floor.
5. Zone valves - located at eye level along a corridor wall for control of specific areas.

These valves allow for three basic types of shutdowns:

1. Complete shutdown - usually done to tie-in a future line to the main or for repairs to the bulk supply source.
2. Riser shutdown - usually done for modifications to an area of the hospital supplied by a single branch (or riser) off the main line.

   This most frequently involves service, replacement, or movement of zone valves.
3. Zone shutdown - usually done when desired remodeling and repairs are downstream of specific zone isolation valves.

Prior to any shutdown, the valves required to isolate the construction area are located and tested for internal leakage. Leaky valves can allow nitrogen used in the brazing process to enter and contaminate adjacent zones, or can prevent the plumbers from achieving the gas concentrations within the pipeline required for brazing (0% O_2, 100% N_2).

Once the contractor determines the extent and duration of shutdown required, the services affected by the shutdown should meet with the contractor to decide on the optimum time and date for the shutdown, to choose a method for supplying medical gases to each patient until the central gas supply is restored, and to define equipment, manpower, and gas supply requirements for that interval. If the shutdown will affect relatively few patients, the simplest alternative supply is through individual supply cylinders, regulators, and backup cylinders for each patient. Patients on ventilators require multiple supply tanks since a single Bear or Servo ventilator uses an "H" cylinder every 4 hours.[3] When larger areas of the hospital are involved, the task of coordinating equipment, supplies, and staff can become very complicated and expensive.

Another acceptable method of supplying the entire system or a portion of a system during a shutdown is to back-feed sections of the MGPS isolated by closing valves either at the riser, branch lines, or zones. Gases are backfed into these sections through inlets placed downstream of the valves. Some such inlets may already exist, such as the Emergency Oxygen inlet which is often used when work is performed on the bulk oxygen supply. Frequently though, inlets need to be installed prior to the planned shut-down. This usually requires a more limited zone shutdown to add an 1/8" collar inlet downstream of a zone valve. The contractor usually adds these collars to zones which receive little or no use to minimally affect patient care. The inlets must be capable of supplying the flows required by the isolated section without a significant pressure drop or equipment may not function properly. If adequate flow cannot be supplied through a single inlet, the area to be isolated can be broken down into multiple isolated zones, each with an inlet, to meet the anticipated total flow

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Planning for Gas Shutoff Complex but Reduces Safety Risk

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required to provide an adequate alternate supply for each patient's needs.

Though not recommended, some MGPS outlets are used as inlets to back-feed a zone. This is generally considered risky as most outlets are flow limited as a result of their relatively small internal diameter. The use of outlets requires careful verification of adequate back-feed flow capacity prior to their use for a shutdown.

The flow requirements and the expected duration of the shut-down determine the type of alternative gas supply chosen. Large stainless steel containers filled with liquid oxygen, called Liquid Dewars, supply large volumes of oxygen, but are limited in the peak flow they can deliver. High pressure cylinders manifolded together in a "six pack" contain smaller volumes of gas, but are capable of much higher peak flows. Combinations of Dewars and "six packs" are sometimes used when high peak flow and high volume use are anticipated. A Y-adapter with check valves attaching the back-feed inlet to the tank supplies permits easy change-over of tanks.

Based on the alternate gas supply method chosen, each affected service notifies, trains, and schedules adequate numbers of staff to handle any potential problem during the shutdown. Adequate supplies of equipment and gas sources are ordered and a plan for distribution developed. Table 1 contains a set of questions often used to help determine the equipment and gas supply requirements. If back-feeding a zone is planned, local pipeline supply alarms, especially in critical care areas and the operating rooms, must be tested for proper function. Meanwhile, the MGPS contractor obtains all pipeline components, prefabricating and pressure testing those portions of the project that can be done in advance. The contractor reviews the shutdown valving plan and details the installation plan including the brazing process. He then briefs his installers on the plan and prepares all tools and equipment required during the installation.

Table

1. How many patient beds will be affected by the shutdown?
2. Of these beds, how many will be occupied by patients requiring pipeline supplies? Which pipeline supplies will be shutdown?
3. How many patients affected by the shutdown will be on ventilators?
4. How many and what brand of ventilators do you use?
5. How many operating rooms will be affected by the shutdown? What OR pipeline supplies will be affected? Which OR pipeline supplies will require alternate sources?
6. How many emergency room beds will be affected by the shutdown?
7. Based on the alternate supply technique chosen, what type and how many flow regulators are needed for floor beds? For ICU beds? For the ORs?
8. Based on the expected maximum duration of the shutdown, what type of gas supply source and how many will be needed for floor beds? For ICU beds? For ORs?
9. How many support stands are needed? Transportation carts? Y-pieces? What other special equipment is required?
10. How much liquid nitrogen will be required for the purge?
11. How many trained staff can be available for the shutdown? How long can they be available? What training have they had?
12. How many personnel will require radio communication equipment?

Communications Key

The shutdown process begins at the prearranged time only after all supervisors are notified the construction crew is ready, a credentialed Medical Gas System Certifier is present, and adequate alternate gas sources are in position. Communication by radio is essential to coordinate the shutdown process. First, the alternate gas supplies are activated and checked to see that they are capable of supplying the gas needs of all patients affected by the shutdown. These alternate gas supplies are closely monitored throughout the shutdown process and replaced as they become depleted. Once it is verified that patients are adequately supplied from the alternate gas supplies, valves upstream and downstream from the area undergoing modification are closed to isolate the construction zone. These valves should be located by the contractor in advance of the shutdown. With valve closure, the construction crew begins work on the pipeline. Components of the planned modifications are cleaned carefully, then assembled. Prior to brazing, the pipeline is purged with an inert gas, usually nitrogen, until all oxygen is removed. This prevents the formation of copper oxide scale inside the pipeline during the brazing process.

After brazing is completed, the isolated construction zone undergoes pressure testing. If no leaks are found, the nitrogen in the pipeline is then purged using backflow from branch lines (sequentially) and/or the primary source until completely removed from the pipeline system. The primary source is left on-line, and the final stage of the shutdown process - recertification - begins.

Recertification involves purity and crossover testing of all outlets in the construction and immediately adjacent zones. An independent, credentialed Medical Gas System Certifier should perform these tests and document that each process and procedure of the shutdown was performed correctly. If problems are detected during testing, the installers remain available to correct system flaws or replace malfunctioning pipeline components. As zones are recertified after purity testing, patients are switched from the alternate sources back to the primary gas pipeline system. Upon completion of the recertification testing, all equipment is removed, and all parties - the contractor, the institution, and the Certifier - must prepare reports on the shutdown.

Thus, the process of shutting down the MGPS is a complex task that potentially exposes patients to greater risks. Good communication and close cooperation between the contractor and institution personnel help to minimize the risks to patients. Uninterrupted medical gas service to patients is a requirement in any shutdown. The anesthesia team needs to understand the MGPS and become an active participant in any shutdown process to maximize safety for their patients.

Guidelines for Planned Medical Gas System Shutdown

Project Definition and Preparation: The goal is to produce a comprehensive written plan of action, and make preparations for the shutdown.

1. Define scope of project. (Institution)
2. Obtain up-to-date plans of the MGPS as actually constructed. (Institution)
3. Determine the areas of the MGPS that will require shutdown. (Contractor)
4. Estimate duration of the required shutdown. (Contractor)
5. Notify affected areas of proposed shutdown. (Institution)
6. Meeting of affected services and contractor to:
   a. Set date and time for shutdown. (Joint)
   b. Choose method for alternate gas supply. (Joint)
   c. Determine equipment and gas supply needs. (Joint)
7. Order equipment and gas supplies. (Either)
8. Coordinate and train staff for shutdown procedure. (Institution)
9. Define and order components for MGPS modification. (Contractor)

Continued on Next Page

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Gas Shutdown Guidelines Help Cut Danger

Continued from Preceding Page

10. Prefabricate and pressure test all component assemblies that can be done in advance. (Contractor)
11. Define assembly procedure and preparation process for brazing. (Contractor)
12. Organize and brief installers on plan and policies. (Contractor)
13. Prepare necessary tools, equipment, and material. (Contractor)
14. Arrange for Medical Gas System Certifier. (Joint)
15. Pre-shutdown modifications to MGPS (inlets). (Contractor)

Shutdown Procedure: The goals are a smooth, uninterrupted transition to alternate gas supplies for all patients affected by the shutdown, along with efficient modification to the MGPS.

1. Notify supervisors in all affected areas of the planned shutdown. (Institution)
2. Distribute alternate gas sources and necessary equipment. (Either)
3. Close zone valves and transfer to alternate gas supplies. (Institution)
4. Assure all patients are provided for throughout the procedure. (Institution)
5. Commence shutdown of primary supply. Notify installers. (Institution)
6. Vent system gas and purge with nitrogen. (Contractor)
7. Perform planned modifications, assemble components. (Contractor)
8. Purge assembly until O_2 content 0%. (Contractor)
9. Verify contents of piping assembly. (Certifier)
10. Braze joints. (Contractor)
11. Pressure test system when done. (Certifier)
12. Vent nitrogen out of system, flush out with primary source and/or backflow from branch lines. (Contractor)
13. Put primary supply back on-line. (Institution)
14. Notify supervisors that construction is completed. (Institution)

Recertification: The goals are rapid purity checking to detect system flaws, correct them, and transition patients back to the primary supply.

1. Purity checking of outlets in zones affected by the shutdown. (Certifier)
2. If flaws or other component problems are detected, repair. (Contractor)
3. Return zones to main supply if purity checks OK. (Institution)
4. Discontinue alternate sources, remove equipment for return. (Institution)
5. Remove construction equipment, debris, tools. (Contractor)
6. Reports of shutdown procedure including purity checks. (All three)
7. File copies of summary report and purity checks. (Contractor)

Dr. Peterson is Assistant Clinical Professor of Anesthesiology at the University of Arizona, Phoenix campus, and Dr. Evans is President of Medical Gas Management, Inc., Bethany, Oklahoma. Both are members of the APSF Subcommittee on Medical Gas Vacuum Systems.

References

1. Feely TW, Hedley-Whyte J: Bulk oxygen and nitrous oxide delivery systems: design and dangers, Anesthesiology 44:301-305, 1976.

2. Moss E. APSF Subcommittee on Medical Gas Systems, April 4, 1994 Meeting agenda.

3. Wentling DG. Important Considerations Prior to Hospital Shutdown. BOC Healthcare Memo.

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Eliminating Water In Medical Air Systems

By: Edwin C. Borkey, P.E.

A Fluid Energy "Technical Report"

Background -- With the adoption of the 1993 edition of the Standard for Healthcare Facilities (NFPA 99)[1], hospitals are required to install in-line hygrometers to continuously monitor the dew point of their Medical Air systems. Specifically, the code requires the dew point not to exceed 39°F (+4°C) and the system to provide an audible alarm for any dew point level above the alarm point.

For many hospital engineers, this seemingly minor modification has resulted in unanticipated problems. After installing a dew point monitor, it has not been uncommon for the hospital to experience frequent dew point alarms. In fact, the problem has been so pervasive that the only known solution for many engineers has been to simply disconnect the monitor.

It is the intent of this paper to provide hospital engineers with an understanding of the causes of this problem and to discuss several proposed solutions that will allow the hospital to remain in full compliance with NFPA 99.

What is Dew Point? -- Dew point is the temperature at which air and other gases can no longer hold water in a vapor state[2]. For example, if a Medical Air system has a dew point of 39°F and the compressed air dry bulb temperature remains above 39°F, the water in the air will remain in a vapor state. No liquid water will condense. However, if the air temperature is allowed to cool below 39°F, liquid water will be present in the Medical Air.

The Typical Medical Air System -- Before addressing solutions to the problem of high dew point alarms, it is important to first understand how the different components within a medical compressed air system affect dew point. Figure 1 shows a typical, NFPA 99 code compliant, duplexed medical compressed air system.

As shown in Figure 1, the NFPA also mandates continuous in-line monitoring of dew point downstream of the line pressure regulators[4].

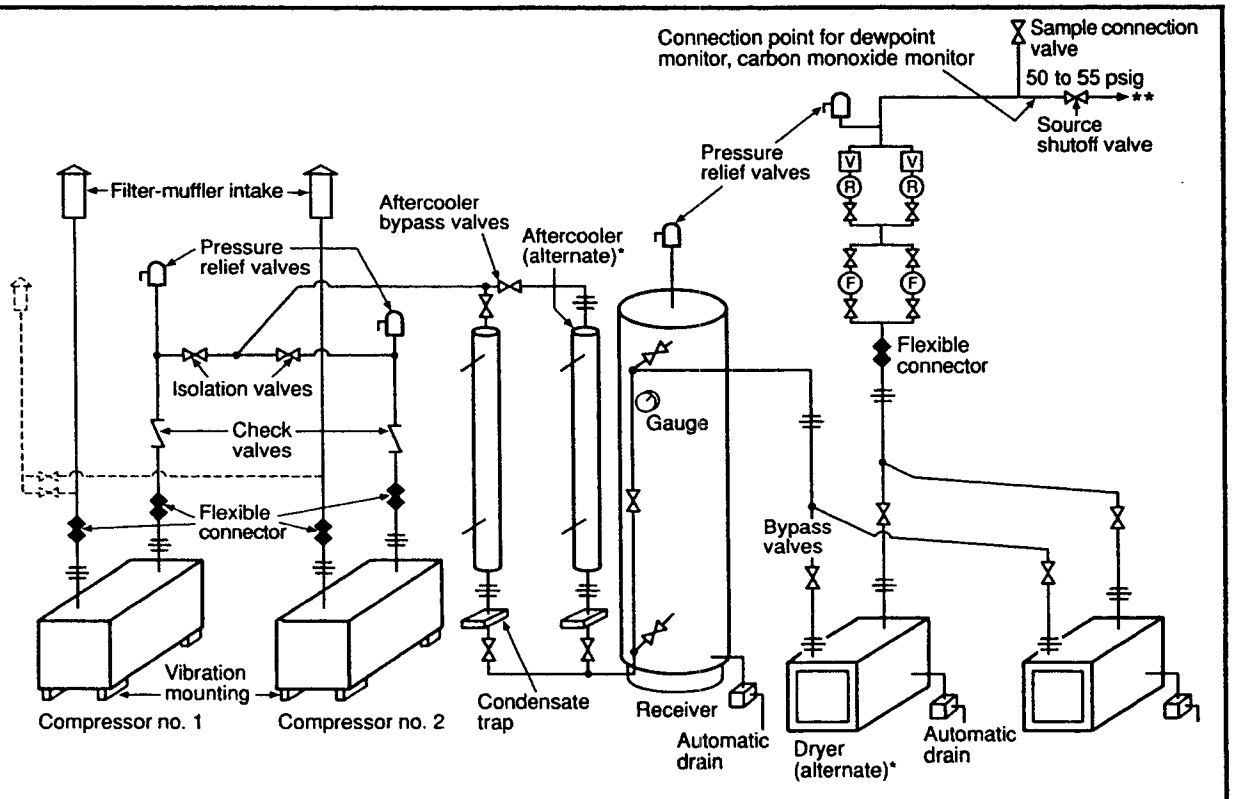

FIGURE 1 - TYPICAL DUPLEX INSTALLATION[3]

In analyzing the problem of high dew point alarm, it is fundamentally important to understand the variations in Medical Air pressure, dry bulb temperature, and dew point temperature at all points within the medical compressed air system. Figure 2 plots these variables at all points in the system beginning with the assumption of 85°F intake air at 50% relative humidity which has a corresponding dew point temperature of 63°F.

the cooling process occurs within the aftercooler where discharge temperatures are reduced to approximately 95°F and bulk amounts of water are removed. When the air temperature within the aftercooler falls to 135°F, 100% saturation is achieved and water vapor begins to precipitate. As the air passes through the discharge piping and air receiver, further cooling occurs which results in an inlet air temperature to the air dryer of 85°F. At

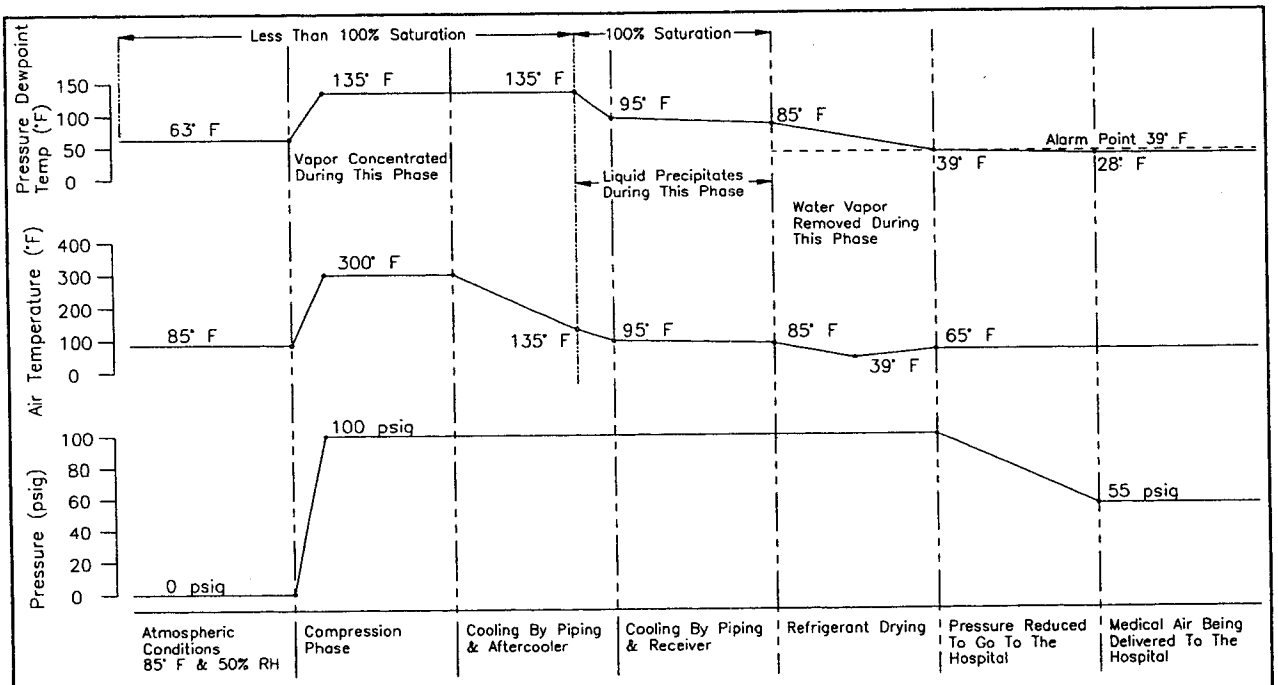

FIGURE 2 - VARIATIONS IN AIR PRESSURE, TEMPERATURE, AND DEW POINT.

The compression process begins with "outside" atmospheric intake air entering the compressor through the inlet air filter. As the air is compressed to 100 psig, the dry bulb temperature increases due to heat generated during compression. With oil-less type reciprocating compressors, the resulting heat of compression yields discharge temperatures of approximately 300°F. The dew point at this stage of the process increases from 63°F at intake to 135°F at discharge as the water vapor pressure rises according to the compression ratio. With water sealed, liquid ring type systems, the resulting water carryover may be significantly higher when additional sealing water passes downstream.

As the air exits the compressor at 300°F, various stages of cooling occur. The first stage of this stage in the process, the dew point of the Medical Air is also 85°F.

The final stage in the cooling process is performed by the air dryer. Traditionally, most hospitals have used refrigerant type air dryers. Provided the liquid separation and subsequent draining system is 100% efficient, this type of dryer should be capable of producing a 39°F pressure dew point. As the air passes through an air-to-refrigerant heat exchanger, it is chilled to approximately 39°F. In order to prevent pipe sweating, it then moves back through the air-to-air heat exchanger to be re-heated to a temperature of 65°. The air-to-air heat exchanger also serves the dual purpose of pre-cooling the inlet air. As the air exits the dryer, the expected dew point should be 39°F.

Finally, the air is filtered and regulated down to a line pressure of 55 psig. As a result of the reduction in water vapor pressure, which occurs during the expansion of the air from 100 psig to 55 psig, the final dew point is even further lowered to 28°F.

Seemingly, the resultant 28°F pressure dew point at a line pressure of 55 psig is well below the alarm condition of 39°F and should result in satisfactory system operation. Why then has the problem of high dew point alarm been so troublesome to hospital engineering and maintenance personnel throughout the country?

The Problem -- As Medical Air systems were analyzed in numerous field test sites[5], it became readily apparent that most incidents of recorded high dew point alarms occurred during periods of low Medical Air demand. Specifically, as shown in Figure 3, when air demand fell to levels below 20% of total system capacity, high dew point alarms could be predicted.

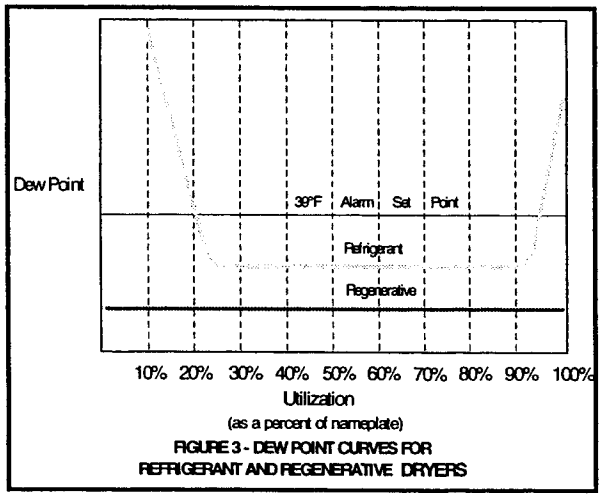

FIGURE 3 - DEW POINT CURVES FOR REFRIGERANT AND REGENERATIVE DRYERS

To fully understand why high dew points occur during periods of low demand, refer to the refrigerant dryer schematic shown in Figure 4. Once the compressed air passes through the air-to-refrigerant heat exchanger and is chilled to 39°F, it then is directed to a moisture separator to drop out any condensed liquids.

Under normal operation at flows above 20% of nameplate capacity, the temperature of the air inside the moisture separator remains cool. Consequently, the water collected in the separator bowl stays in a liquid state. However, under low

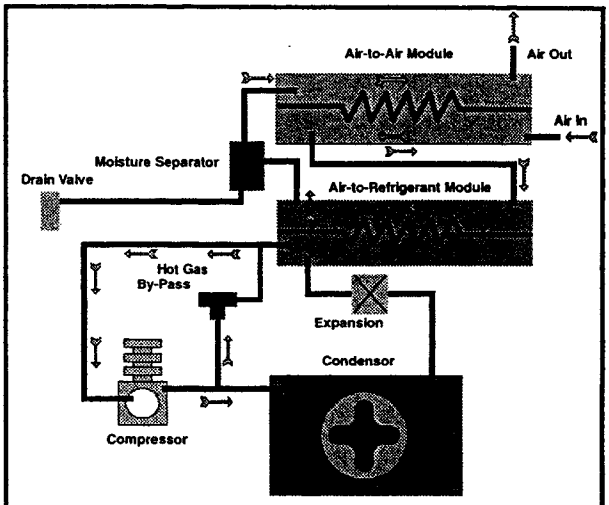

FIGURE 4 - REFRIGERANT DRYER SCHEMATIC

flow conditions, the normally cold air movement through the separator is slowed to such a point that the air temperature inside the bowl warms to near ambient conditions.

When this happens, any accumulated liquid water in the separator bowl evaporates back into the Medical Air and passes downstream. The unavoidable result is high dew point alarm.

Since low flow conditions are to be expected in most Medical Air applications[6] and refrigerant dryers often have difficulty maintaining consistent dew points under low flow conditions, an alternative drying method needs to be examined.

The Quick Fix -- Faced with an unmanageable number of dew point alarms and a shortage of answers, many hospital engineers have been forced to improvise interim solutions. One of the more common suggestions has been to place an artificial load on the Medical Air system.

An artificial load can be accomplished by bleeding to atmosphere a portion of the Medical Air such that the total system demand exceeds 20% of rated capacity. With this approach, the air temperature within the separator bowl remains cool allowing the condensed water to stay in liquid form where it can be drained from the system.

However, by creating this constant artificial load, the compressors are forced to run much more frequently than normal. This will inevitably shorten compressor life as well as unnecessarily.increase power costs. At best, this can only be described as a short term solution.

The Optimum Solution -- In other varied industries where consistently low dew points are required, desiccant or twin-tower regenerative-type dryers have become the technology of choice.

Why then are so few desiccant dryers used in Medical Air systems within the U.S.? Primarily, most Medical Air compressor manufacturers have avoided desiccant systems for three historical reasons:

1. Initial cost
2. Purge air losses
3. Physical size.

However, with the latest advances in desiccant dryer technology, all three of these objections may be eliminated or greatly minimized.

Today, innovations in design allow the use of much smaller desiccant towers which reduces both the initial capital cost and the physical size. Additionally, major improvements in technology can now provide purge control systems that significantly reduce purge air requirements in systems with widely varying flow capacities. Consequently, desiccant or regenerative drying has become increasingly more popular for many Medical Air applications.

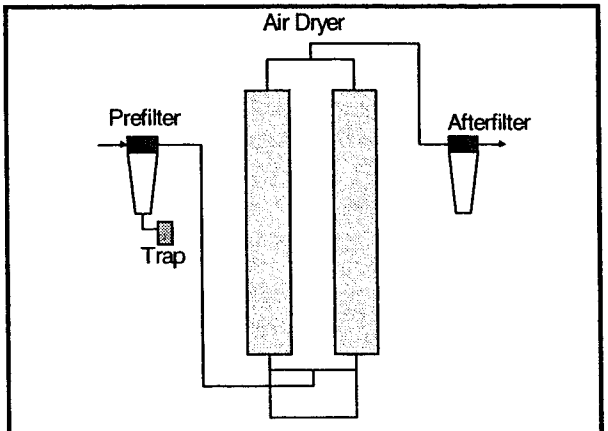

FIGURE 5 - HEATLESS REGENERATIVE

As shown in Figure 5, heat-less regenerative drying systems basically consist of three components:

1. Coalescing pre-filter
2. Heat-less regenerative dryer
3. Particulate afterfilter

The main function of the coalescing pre-filter is to remove liquids, including droplets, aerosols, and mists. The secondary purpose is to remove particulate which helps maintain dryer operating efficiency.

Immediately downstream of the pre-filter is the heat-less regenerative or, as it is frequently called, desiccant dryer. Regenerative dryers consist of two pressure vessels filled with an adsorbent desiccant material, usually activated alumina.

While compressed air passes through one vessel for dehydration, the off-line vessel is regenerated by passing a small slip stream of dry compressed air across the saturated portion of the desiccant. In this way, the dry compressed air desorbs water vapor off the desiccant and expels it to atmosphere[7]. By frequent alternation of the pressure vessels from the "drying" to "regeneration" modes, a continuous discharge stream of dry compressed air is achieved.

In comparison to refrigerant dryers which produce nominal 39°F pressure dew points, heat-less regenerative dryers are capable of producing pressure dew points as low as -100°F.

However, for Medical Air applications such extraordinarily low dew points are not required. Optimum designs will maintain dew points within a range of -10°F to +20°F, well below the mandated alarm point of +39°F (+4°C).

In addition to the benefit of low dew point production, regenerative dryers are also operationally effective at low flow conditions commonly associated with Medical Air systems as shown in Figure 3.

Furthermore, from an energy perspective, properly sized and designed regenerative systems also consume less power than corresponding refrigerant dryers in most Medical Air systems. For example, non-cycling refrigerant dryers consume 100% of full load power, regardless of the compressed air demand. Because many Medical Air systems operate below 30% utilization, regenerative dryers with purge-saving control systems actually consume less energy than refrigerant types.

Summary -- Hospitals usually have three choices when choosing medical compressed air drying equipment. The purpose of this paper is to alert hospital engineers and respiratory therapists about the consequences of these choices as they relate to health care.

Table 1 summarizes the benefits and potential problems with refrigerant, heat-less regenerative, and the improved regenerative dryer design.

Clearly the future in drying medical compressed air lies with well designed regenerative drying systems.

TABLE 1 - SUMMARY OF MEDICAL AIR DRYING OPTIONS

	DRYER TYPE		
Hospital Needs	Refrigerant	Heat-Less Regenerative	Improved Regenerative Dryer
Low dewpoints	No	Yes	Yes
Effective at all loads	No	Yes	Yes
Energy efficient	No	Maybe	Yes
NFPA compliant	Maybe	Maybe	Yes
Small footprint	Maybe	Maybe	Yes
Simple installation	Maybe	No	Yes
Minimal maintenance	Yes	Maybe	Yes
No CFC's	No	Yes	Yes
Low first cost	Yes	No	Yes

References

[1] Standard For Health Care Facilities, NFPA 99, 1993 Edition, National Fire Protection Association.

[2] J.P. Holman's Textbook of Thermodynamics, Third Edition, 1980, defines dew point as "the temperature at which the vapor starts to condense when the (gas) mixture is cooled at constant pressure."

[3] Standard For Health Care Facilities, NFPA 99, 1996 Edition, National Fire Protection Association, Page 42, Figure 4-3.1.9.

[4] Standard For Health Care Facilities, NFPA 99, 1993 Edition, National Fire Protection Association, Page 50, Table 4-3.1.9.8 shows the need for continuous dew point alarm. The 1996 Edition also mandates continuous dew point alarm on page 44.

[5] In a field survey conducted by Fluid Energy in February, 1996, 31 of 59 hospitals reported frequent dew point alarms or water problems in Medical Air.

[6] Medical Air sizing programs used in the United States and Canada usually result in conservatively sized systems. As a result, compressed air dryers often operate under light loads.

[7] Further technical details on heat-less regenerative dryers, including a discussion on adsorption and desorption can be found in Fluid Energy's technical paper titled "Heat-Less Regenerative Dryers-How Do They Work?"

About the Author

Edwin C. Borkey is sales manager of Fluid Energy, Charlotte, NC. He is a registered professional engineer and holds a B.S. degree is mechanical engineering from Ohio Northern University. He has over fourteen years experience with industrial and process compressors, dryers and filters.

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IN REPLY REFER TO

BUMEDINST 6710.66
BUMED-42
10 Jan 90

BUMED INSTRUCTION 6710.66

From: Chief, Bureau of Medicine and Surgery
To: Ships and Stations Having Medical Department Personnel

Subj: DELIVERY AND ADMINISTRATION OF OXYGEN FOR MEDICAL USE

Ref: (a) DODDIR 6055.10 of July 26, 1989 (NOTAL)
(b) United States Pharmacopeia, 21st Revision of 1 Jan 85

Encl: (1) Outline Procedures for Testing Oxygen Concentration
(2) Anesthesia Apparatus Preuse Checklist

1. Purpose. To implement reference (a) and provide additional guidelines on the delivery and administration of medical oxygen.

2. Background. Reference (a) requires all medical treatment facilities and dental treatment facilities to:

a. Check the amount and concentration of bulk liquid oxygen (LOX) at time of delivery, before it is either introduced to a central system or administered to a patient.

b. Test anesthesia and analgesia equipment before use.

c. Provide written plans in case the central oxygen system is disrupted.

3. Policy

a. Oxygen Concentration and Testing

(1) LOX must contain not less than 99 percent oxygen.

(a) The gas phase of LOX must be tested. Enclosure (1) provides testing guidelines for various circumstances. Changes may be made to meet local conditions, for instance, available test equipment.

(b) Due to test equipment limitations, 95 percent or higher concentration is acceptable evidence of purity when testing LOX in field conditions. Available field test equipment

is a commercial, battery powered, polargraphic, paramagnetic, or equivalent analyzer with a full scale accuracy of no less than plus or minus 2 percent.

(c) Vendors' certification that the LOX meets the requirements of reference (b), may be substituted for testing for carbon dioxide, carbon monoxide, and particulate matter.

(2) Molecular sieves must meet the "Oxygen 93 Percent" monograph of reference (b): between 90 and 96 percent oxygen by volume. Appropriate authorities must certify the unit capable of producing 93 percent oxygen on delivery, before long-term storage, when placed into service, and annually. In storage, annual maintenance and operability checks must be performed.

(3) Keep LOX test records, vendor certifications, and molecular sieve certifications for 2 years to provide an audit trail for Joint Commission on the Accreditation of Healthcare Organizations, Inspectors General, and other authorities. Destroy after 2 years.

(4) Aviation breathing oxygen may be substituted for medical oxygen in all cases, if it meets the requirements of this instruction. Humidification may be required with prolonged use.

b. Oxygen Administration

(1) When a specific concentration is prescribed, oxygen must be monitored at the point of administration. The patient's record will indicate the flow rate and concentration.

(2) Test all anesthesia and analgesia equipment on delivery of new items, repair of existing equipment, and before patient use. Enclosure (2) provides a guideline. With appropriate peer review it may be changed to meet local conditions, for instance, equipment design, technology changes, and variations in clinical practice. Testing will be documented in the equipment maintenance jacket, or in the patient's medical record, as appropriate.

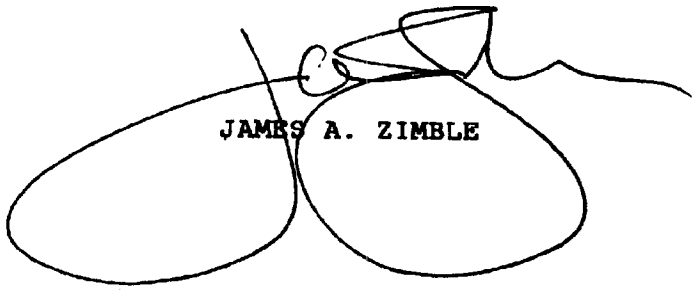
c. Emergency Plan. Each activity with a central oxygen supply system must maintain a written emergency plan to deal with a system malfunction. The plan will describe any alarms and the actions to be taken when an alarm is activated. The plan must identify those clinical areas that will need an alternate oxygen supply until the central oxygen supply system is functioning properly.

4. Action. Commanding officers, officers in charge, or other proper authority must:

a. Appoint in writing individuals to test LOX deliveries and accept or reject deliveries. If necessary, appoint individuals to certify that molecular sieve equipment meets the "Oxygen 93 percent" monograph in reference (b).

b. Establish procedures to ensure that anesthesia and analgesia equipment are properly tested and that testing is documented. Review enclosure (2). Document the review and issue in a "Policy and Procedure Manual" or similar publication.

c. Maintain a central oxygen supply system malfunction plan.



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OUTLINE PROCEDURES FOR TESTING OXYGEN CONCENTRATION

This is a generic procedure to test oxygen (O_2) concentration. Commands may change these procedures to fit different makes and models of test equipment and to meet unique local requirements.

1. General Equipment Requirements

a. Battery powered O_2 analyzer.

b. Test gas reservoir. An O_2 nebulizer bottle with a 15-22 mm outlet is preferred. Heaters are not required.

c. Back flow compensated O_2 flowmeter (two each).

d. O_2 regulator. One if testing a 50 pounds per square inch gauge (psig) source, two if source is greater than 50 psig.

e. Calibration gas or known 100 percent O_2 source.

f. Low pressure connecting hose, O_2 diameter indexed safety system (DISS fittings) (two each).

g. O_2 cylinder truck or cart. (One for each cylinder.)

h. Grounding cable, 15 to 20 feet with extra large alligator type clips on each end.

2. Safety Precautions

a. Always work in a well ventilated space away from open flames or sparks. Ventilation avoids the buildup of O_2 that is released by leaks or during the testing process.

b. Use only tools designed for use with O_2 delivery systems. Tools must be nonsparking, oil and contamination free, and reserved for use with O_2 only.

c. Area must be clean and free of combustibles, especially oil and other petroleum products. In an O_2 enriched atmosphere, normally noncombustible material will burn easily.

d. Always store cylinders with safety caps firmly screwed in place. The safety cap protects the most vulnerable part, the cylinder valve, in case the cylinder drops or falls.

e. Always secure cylinders by chains or racks when in an upright position. When transporting, secure to a specially designed cylinder truck or cart.

f. Clear the cylinder outlet of dust and foreign matter by briefly opening the cylinder valve before attaching to regulators or piping manifolds. Always point outlets away from yourself and others to avoid injury by foreign material in the outlet.

g. Open valves slowly, before opening to full flow. The rush of high pressure gases can create temperatures sufficient to support combustion. Opening valves slowly will reduce this hazard. Opening to full flow will ensure that full flow capacity of regulators can be achieved.

h. Never drop or roll compressed gas cylinders because this can rupture the cylinder. Age, prior abuse, exposure to heat, and other factors can reduce the cylinder's durability, despite built-in safety margins. Rolling the cylinder creates stresses for which the cylinder was not designed.

i. Never use compressed gas cylinders, empty or full, as rollers or axles.

j. Always assemble and test O_2 administration equipment away from patient care areas.

3. Assemble Reference or Calibration Gas Source

a. Secure each cylinder to a cylinder truck or cart.

b. Open the cylinder valve slightly to clear any foreign matter. Face the opening away from yourself and others. The valve will clear within 1 second and should then be closed.

c. Fit a O_2 regulator to reference or calibration gas cylinder and tighten the connection with a proper wrench.

d. Attach a pressure compensated flow meter to the low pressure outlet of the O_2 regulator. Tighten the flowmeter connection with a proper wrench.

e. Attach an O_2 nebulizer bottle to the outlet of the flowmeter and tighten hand-tight.

f. With the flow valve opened slightly, slowly open the cylinder valve to fully open. The meter should register flow and the flow should be heard. Close the flowmeter valve so the flow stops. Do not over tighten the flowmeter or use force to stop the flow! Over tightening this valve will damage the flowmeter. If the flow does not stop with finger tight pressure, turn the flowmeter in to medical repair and use another flowmeter.

4. Calibrate the Oxygen Analyzer

a. Review the manufacturer's calibration instructions.

b. Open the reference or calibration gas flowmeter valve until a flow of 10-12 liters per minute through the nebulizer is indicated. Allow the nebulizer jar to be flushed with O_2 for at least 15 seconds before sampling.

c. When the manufacturer's instructions require a sample of a 99 or 100 percent source, place the analyzer probe in or on the nebulizer jar and calibrate the high-point of the instrument.

d. Low-point calibration of the analyzer is performed using ambient air. Ensure that you are well clear (20-25 feet) of other O_2 sources while performing the low-point calibration.

5. Assemble the Test Gas Assembly and Test the Concentration
This procedure will vary with the source of the gas to be tested.

a. LOX Delivery Truck With a 50 psig Regulator

(1) Attach a nebulizer jar to the outlet of a flowmeter. Tighten connection hand-tight.

(2) Attach a low-pressure O_2 hose to the inlet of the flowmeter. Tighten connection hand-tight.

(3) Have the delivery truck driver attach a ground cable from the delivery truck to the metal connection on the test gas flowmeter. This cable will dissipate any static charges and reduce the hazard of sparks in an O_2 enriched atmosphere.

(4) Have the delivery truck driver attach the opposite end of the low-pressure O_2 outlet to the regulated 50 psig outlet on the truck.

(5) Sample the head gas contents of the delivery truck.

(a) Open the flowmeter control valve slightly.

(b) Ask the driver to open the truck's sample port.

(c) Adjust the flowmeter for a flow rate of 10-12 liters per minute and flush the test gas nebulizer jar for at least 15 seconds. Test the contents of the nebulizer jar as specified by the manufacturer and record the results.

(6) Have the driver close the sample port valve and allow the pressure to bleed off the test circuit through the flowmeter. When the flow returns to zero, request the driver remove the low-pressure hose from the truck. Wait 30 seconds to allow dissipation of gases from the area, then have the driver remove the grounding cable.

(7) Remove all test equipment from the area. Record the liquid level of the LOX tank before the filling operation. Stand well clear of the LOX tank and truck during the filling operation.

(8) Record the liquid level of the LOX tank after the driver has disconnected the transfer hoses.

b. LOX Delivery Truck Without a 50 psig Regulator: Procedure is similar to paragraph 6a; except, have the driver place a single stage O_2 regulator on the sample port. Connect the distal end of the low-pressure O_2 hose to the output of the regulator.

c. High Pressure Oxygen Cylinders

(1) Ensure O_2 analyzer has been calibrated with a known 100 percent O_2 source. Assemble an O_2 test circuit with the following parts: 50 psig O_2 regulator, pressure compensated O_2 flowmeter, and an O_2 nebulizer bottle.

(2) Secure all cylinders in a cylinder truck or cart, or chain in a compressed gas cylinder rack.

(3) Remove the safety cap from the cylinder. Clear the cylinder valve by briefly opening the valve for 1 second.

(4) Attach O_2 test circuit to cylinder to be tested and tighten the connection with a proper wrench.

(5) With the flowmeter valve opened slightly, open the cylinder valve slowly. Adjust the flowmeter to 10-12 liters per minute flow and flush the test gas nebulizer bottle for at least 15 seconds. Sample the nebulizer bottle contents as specified by the O_2 analyzer manufacturer and record the results.

(6) Close the cylinder valve and allow the pressure to bleed off the test circuit through the flowmeter. When the flow returns to zero, remove the O_2 test circuit from the cylinder with an appropriate wrench and reinstall the cylinder safety cap.

d. Molecular Sieves

(1) Ensure O_2 analyzer has been calibrated with a known 100 percent O_2 source. As appropriate, assemble an O_2 test circuit with the following parts: 50 psig O_2 regulator (if concentrator outlet pressure is higher than 50 psig), pressure compensated O_2 flowmeter, and an O_2 nebulizer bottle.

(2) Clear the O_2 concentrator outlet by briefly opening the control valve for 1 second.

(3) Attach O_2 test circuit to the outlet and tighten the connection with a proper wrench.

(4) With the flowmeter valve opened slightly, open the cylinder valve slowly. Adjust the flowmeter to 10-12 liters per minute flow and flush the test gas nebulizer bottle for at least 15 seconds. Sample the nebulizer bottle contents as specified by the O_2 analyzer manufacturer and record the results.

(5) Close the outlet control valve and allow the pressure to bleed off the test circuit through the flowmeter. When the flow returns to zero, remove the O_2 test circuit from the concentrator with a proper wrench.

ANESTHESIA APPARATUS PREUSE CHECKLIST

This checklist must be completed before administering anesthesia. It may be locally changed due to differences in equipment design and variations in clinical practice. Such local changes must have appropriate peer review. The review must be documented and the checklist issued in a "Policy and Procedures Manual" or similar publication. Refer to the operator's manual for special procedures and precautions.

1. Inspect anesthesia apparatus:

    a. Identification number.

    b. Valid inspection sticker.

    c. Undamaged flowmeters, vaporizers, gauges.

    d. Complete supply hose set.

    e. Undamaged breathing system.

    f. Adequate carbon dioxide (CO_2) absorbent.

    g. Correct mounting of cylinder in yokes.

    h. Presence of cylinder wrench.

2. Inspect and turn on electrical equipment requiring warmup.

3. Connect waste gas scavenging system. Adjust vacuum.

4. Check that:

    a. Flow control valves are off.

    b. Vaporizers are off and filled (but not overfilled).

    c. Filler caps are sealed tightly.

    d. CO_2 absorber by-pass (if any) is off.

5. Check O_2 supplies

    a. Disconnect pipeline supply and return cylinder and pipeline pressure to zero with O_2 flush valve.

    b. Open O_2 cylinders; check pressure; close cylinder and observe gauge for evidence of high pressure leak.

c. Return system pressure to zero with O_2 flush valve.

d. Repeat steps 5b and 5c for each cylinder.

e. Replace any cylinder under 600 psig. At least one cylinder should be nearly full (approx. 2000 psig).

f. Open less full cylinder.

6. Turn on master valve (if present).

7. Check nitrous oxide (N_2O) cylinder. Use steps 5a and 5b above, but open and close flow control valve to empty piping. N_2O pressure below 700 psig means the cylinder is less than 1/4 full.

8. Test flowmeters

a. Check that the float is at the bottom of the tube with the flow control closed (or at minimum O_2 flow if so equipped).

b. Adjust the flow of all gases through their full range and check for erratic movements of floats.

9. Test ratio protection and warning system (if present). Attempt to create hypoxic O_2/N_2O mixture, and verify correct change in gas flows and alarms.

10. Test O_2 pressure failure system

a. Set O_2 and other gases to midrange.

b. Close O_2 supply cylinder and flush to release pressure.

c. Verify that all flow fall to zero. Open O_2 cylinder.

d. Close all other cylinders and bleed piping.

e. Close O_2 cylinder and bleed piping pressures.

f. Close flow control valves.

11. Test central pipeline gas supplies

a. Inspect supply hoses for cracks and wear.

b. Connect supply hoses, verify color coding.

c. Adjust all flows to at least midrange.

d. Ensure that the supply holds 45-55 psig.

e. Shut flow control valves.

12. Add any accessory equipment to the breathing system: positive end-expiratory pressure (PEEP) valve, humidifier, turbine, etc., if they might be used. If necessary remove after step 18 until needed.

13. Calibrate O_2 monitor:

a. Adjust O_2 monitor to read 21 percent in room air.

b. Test low alarm.

c. Occlude breathing system at patient end: fill and empty several times with 100 percent O_2.

d. Check that monitor is reading nearly 100 percent.

14. Smell inspiratory gas. There should be no odor.

15. Check one-way valves:

a. Inhale and exhale through a surgical mask into the breathing system (individually if possible).

b. Verify unidirectional flow in each limb.

c. Reconnect tubing firmly.

16. Test for leaks in machine and breathing system

a. Close adjustable pressure limiting (pop-off) valve and occlude the system at patient end.

b. Fill system via O_2 flush valve until bag is full, but negligible pressure in the system. Set O_2 flow to 5 liters per minute (l/min).

c. Slowly decrease O_2 flow until pressure no longer rises above 20 cm H_2O. This approximates total leak rate, which should be no greater than a few hundred milliliters per minute (less for closed circuit techniques). CAUTION: Check valves in some machines make it necessary to measure flow when pressure just stops rising.

d. Squeeze bag to a pressure of 50 cm H_2O and verify that the system is tight.

17. Check exhaust valve and scavenger system

a. Open adjustable pressure limiting (APL) valve and observe the release of pressure.

b. Occlude the breathing system at the patient end and verify that negligible positive and negative pressure appears with either zero or 5 l/min. flow and exhaust relief valve (if possible) opens with flush flow.

18. Test ventilator

a. If switching valve is present, test in both bag and ventilator mode.

b. Close APL valve, as necessary.

c. Occlude system at patient end.

d. Test for leaks and pressure relief by appropriate cycling (exact procedure will vary with the type of ventilator).

e. Attach a reservoir bag at the mask fitting, fill system and cycle ventilator. Assure filling and emptying of bag.

19. Check level of patient suction.

20. Check, connect, and calibrate other electronic monitors.

21. Check final positions of all controls.

22. Turn on and set other alarms for equipment to be used.

23. Set O_2 monitor alarm limits.

24. Set airway pressure and volume monitor alarm limits (if adjustable).

Sentinel Event ALERT

Issue 21, July 2001

Medical gas mix-ups

Published for Joint Commission accredited organizations and interested health care professionals, Sentinel Event Alert *identifies the most frequently occurring sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future.*

During the on-site survey of accredited organizations, JCAHO surveyors assess the organization's familiarity with and use of Sentinel Event Alert *information. Organizations are expected to (1) review each* Sentinel Event Alert, *(2) consider the suggestions, as appropriate to the organization's services, and (3) implement the suggestions, or reasonable alternatives, or provide a reasonable explanation for not implementing relevant changes.*

The Joint Commission received two reports of medical gas mix-ups in 2000 that resulted in the death of four patients and injury to five patients. In the past four years, the Food and Drug Administration (FDA) has received four reports that resulted in seven deaths and 15 injuries. In early April 2001, the FDA issued a *Guidance for Hospitals, Nursing Homes, and other Health Care Facilities--Public Health Alert*[1] that focuses on its reports of medical gas mix-ups, their common causes and the FDA's recommendations for preventing occurrences. This alert is being distributed to help spread the word to health care organizations about steps that can be taken to prevent deaths and injuries from compressed gases, which include industrial and medical grade gases. Medical grade gases are considered prescription drugs and include oxygen, compressed air, carbon dioxide, helium, nitrogen and nitrous oxide. These medical gases are either used in medical treatment and procedures, or to power medical equipment. Industrial grade gases should never be used medically. Medical gases come in many different types of vessels, but three of the FDA's four cases involved cryogenic vessels and their connectors, so this alert will focus on the problems associated with those vessels.

Common causes

The FDA's public health alert highlights several common causes in its cases of medical gas mix-ups that are related to 1) lack of proper training of personnel responsible for the delivery, connection or identification of medical grade gas vessels, 2) removal of gas-specific connectors, and/or 3) improper labeling (in one case) or storage of medical gas vessels. Three of the FDA's four cases involved maintenance or delivery personnel who were not trained to recognize built-in safeguards--specifically connection incompatibility. Connectors for cryogenic oxygen vessels are specially fitted so that they are compatible only with oxygen delivery systems. In most cases, the health care organization's personnel responsible for medical gases were not trained to recognize the labeling used to identify the grade or type of gas in vessels. In some cases, medical grade and industrial grade product vessels were stored together, and the wrong grade gas was selected or delivered accidentally.

The FDA, the Compressed Gas Association (CGA) and

medical gas manufacturers are exploring new safeguards, including silver brazed connections on cryogenic vessels that are impossible to remove. The CGA is a safety and standards organization for medical and industrial gases; its membership includes manufacturers of medical and industrial gases and equipment, as well as distributors. In December 2000, the CGA issued *SB-26*[2], a safety bulletin that recommends the use of silver brazed connections on cryogenic liquid cylinders in medical gas service. Other safeguards being considered are standardized color-coding and better labeling of cryogenic vessels. While a health care organization has no control over labeling used by its medical gas supplier or the training of its medical gas delivery personnel, there are measures that an organization can take to help prevent deaths or injuries from medical gas mix-ups.

Expert recommendations

The FDA recommends the following procedures be taken to prevent medical gas mix-ups at health care organizations.

With respect to personnel training, all employees who handle medical gases:

- Should be alerted to and reminded of the possible hazards associated with using medical gas.
- Should be trained to recognize and carefully examine medical gas labels.
- Should be trained to make sure each vessel they connect to the oxygen system bears the proper label--if your supplier uses 360-degree, wrap-around labels to designate medical oxygen.
- Should be trained to connect medical gas vessels properly if they are responsible for changing or installing cryogenic vessels. These personnel should understand how vessels are connected to the oxygen supply systems and be alerted to the serious consequences of changing connections. Adapters must never be used to make a connection.

With respect to equipment and gas storage:

- If your facility receives medical gas deliveries, store medical grade products separately from industrial grade products. The storage area for medical grade products should be well defined with one area for receiving full cryogenic vessels and another area for storing empty

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"Ideally, a practitioner licensed by state law, such as a pharmacist assistant, a pharmacist technician, or a trained designee, should check the gas before use to ensure that the patient is receiving the correct medical grade gas."
*--**Duane Sylvia**, consumer safety officer, FDA Office of Compliance, Center for Drug Evaluation and Research*

vessels.

- The fittings on cryogenic vessels should not be changed under any circumstances. If a cryogenic vessel fitting does not seem to connect to the oxygen supply system fitting, the supplier should be contacted immediately. The vessel should be returned to the supplier to determine the fitting or connection problem.

- Once a cryogenic vessel is connected to the oxygen supply system, but prior to introducing the product into the system, a knowledgeable person should ensure that the correct vessel has been connected properly.

"Ideally, a practitioner licensed by state law, such as a pharmacist assistant, a pharmacist technician, or a trained designee, should check the gas before use to ensure that the patient is receiving the correct medical grade gas," says **Duane Sylvia**, consumer safety officer with the FDA's Office of Compliance at its Center for Drug Evaluation and Research.

Recommendations

JCAHO recommends that organizations address the recommendations with respect to personnel training, equipment and gas storage as listed above.

References

[1]*Guidance for Hospitals, Nursing Homes, and other Health Care Facilities-Public Health Alert*, April 2001; U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research; available at http://www.fda.gov/cder/guidance/4341fnl.htm

[2]SB-26; December 8, 2000; Compressed Gas Association; available for purchase by non-members for $6 at the CGA Web site, www.cganet.com, or by calling 703-412-0900.

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